IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and ABBOTT CARDIOVASCULAR SYSTEMS, INC.,	)	C. A. No. 06-613-SLR
Plaintiffs,	)	
v.	)	
JOHNSON AND JOHNSON, INC. and CORDIS CORPORATION,	)	
Defendants.	)	

PLAINTIFFS' OPENING MEMORANDUM IN SUPPORT OF THEIR MOTION TO ENJOIN DEFENDANT CORDIS FROM PROSECUTING LATER-FILED PARALLEL LITIGATION IN NEW JERSEY

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I. INTRODUCTION

Plaintiffs move to enjoin Defendant Cordis Corporation ("Cordis") from proceeding with a complaint filed by Cordis in the District of New Jersey (the "New Jersey Complaint") on May 15, 2007. In that complaint, Defendant Cordis alleges that XIENCE V, a drug-eluting stent system manufactured by Plaintiffs for coronary angioplasty, infringes U.S. Patent No. 7,217,286 ("the Wright 286 patent").

Before the New Jersey Complaint was filed, Plaintiffs filed a complaint against Defendants, in this Court, seeking a declaratory judgment that the Wright 286 patent is invalid and not infringed by Plaintiffs (C.A. No. 07-259). In addition, months earlier, Plaintiffs filed a complaint against Defendants, also in this court, for a declaratory judgment that other Wright patents, which are directly related to the Wright 286 patent, are invalid and not infringed by Plaintiffs' XIENCE V (C.A. No. 06-613-SLR). Also, before the New Jersey Complaint was filed, Plaintiffs moved (1) to supplement their declaratory judgment complaint or (2) in the alternative, to consolidate the two Delaware declaratory judgment actions (which involve the same parties, the same accused product, and directly related Wright patents) brought by Plaintiffs against Defendants in this Court.

Under well-established precedent, as the first-to-file litigants, Plaintiffs enjoy a "presumptive right" to choose the forum. Plaintiffs selected Delaware as the forum for the patent disputes between the parties. This Court has substantial experience with patent litigation relating to stents for coronary angioplasty including litigation involving these parties. The parties should resolve these matters in this Court where Plaintiffs brought

their first-filed complaints against Defendants. Defendant Cordis should be enjoined from proceeding with the duplicative litigation in New Jersey. Defendant Cordis can assert its compulsory counterclaims for patent infringement in this Court, where Plaintiffs brought the first-filed actions.

II. FACTUAL BACKGROUND

A. Abbott's XIENCE V Drug-Eluting Stent And The Wright and Falotico Patent Families

Plaintiffs Abbott Laboratories and Abbott Cardiovascular Systems (collectively "Abbott") manufacture and sell medical devices for the treatment of coronary artery disease including XIENCE V, a drug-eluting stent system which elutes a proprietary drug called everolimus. Abbott holds an exclusive patent license to use everolimus for drug eluting stents. (D.I. 1, Compl., ¶ 16.) In clinical trials, everolimus has proven superior to other drugs. (*Id.*) Abbott has been manufacturing, and recently launched sales of, XIENCE V.

Defendants, Johnson and Johnson, Inc. and its subsidiary Cordis (collectively "J&J"), are major players in the intravascular stent market. J&J manufactures and sells an intravascular drug-eluting stent called CYPHER. J&J has two families of related patents and patent applications directed to drug-eluting stents. These two families of patents and patent applications are referred to as "the Wright patent family" and "the Falotico patent family" (collectively, "the Wright and Falotico patent families") after alleged inventors Carol Wright and Robert Falotico. The Wright patent family includes, among others, U.S. Patent No. 6,585,764 ("the Wright 764 patent"), U.S. Patent No.

6,808,536 ("the Wright 536 patent"), the newly-issued Wright 286 patent,[1] and pending U.S. Patent Application No. 10/951,385 ("the Wright 385 application"). The newly-issued Wright 286 patent is a continuation of the Wright patents-in-suit (the Wright 536 and 764 patents) as well as the Wright 385 application. (*See* Ex. 5, Wright 286 patent at cover.) The Falotico patent family includes, among others, U.S. Patent No. 6,776,796 ("the Falotico 796 patent"), which is also a patent-in-suit. (*See, e.g.*, D.I. 1 at Ex. C.)

B. In September 2006, Abbott Filed The First Case Relating To XIENCE V And The Wright And Falotico Patent Families

On September 29, 2006, just before launching XIENCE V, Abbott filed a declaratory judgment complaint ("the Original Delaware Complaint") in this Court for three patents in the Wright and Falotico patent families: the Wright 764 patent, the Wright 536 patent, and the Falotico 796 patent (collectively "the Wright and Falotico patents-in-suit"). (D.I. 1 (Civ. No. 06-613-SLR).) In the Original Delaware Complaint, Abbott seeks a declaratory judgment that the Wright and Falotico patents-in-suit are invalid and not infringed by XIENCE V. (*See, e.g.*, D.I. 1, Compl. at 13.) Abbott filed the Original Delaware Complaint due, in part, to J&J's public campaign to cast a cloud

[1] Even though the Wright 286 patent is in the Wright patent family, during prosecution, alleged inventor Wright was dropped as an inventor and Falotico was added. (Ex. 11.) Thus, alleged inventor Falotico appears on the face of the patent instead of Wright. For sake of clarity, this patent is referenced as the "Wright 286 patent" because it is part of that family of patents (even though Wright is no longer a named inventor). In Plaintiffs' Opening Memorandum In Support Of Their Motion For Leave To File A Supplemental Complaint Or In The Alternative To Consolidate Related Cases (D.I. 44) filed on May 15, 2007, the patent referenced herein as the "Wright 286 patent" is referenced as the "Falotico 286 patent." Plaintiffs apologize for any confusion but believe that this nomenclature will be clearer at the end of the day.

over Abbott's ability to market XIENCE V in view of the Wright and Falotico patent families. (*Id.*, ¶¶ 9-49.)

Importantly, in addition to seeking a declaratory judgment regarding the Wright and Falotico patents-in-suit, the Original Delaware Complaint also addressed express infringement charges against XIENCE V made by J&J during the prosecution of still-pending Wright and Falotico patent applications. (*Id.*, ¶¶ 40-47.) Using two examples (one from each family), the Original Delaware Complaint detailed how J&J rushed pending Wright and Falotico patent applications through the Patent Office based on alleged "actual infringement" by XIENCE V. (*Id.*) Specifically, in August 2006, J&J filed at least six "Petitions to Make Special Because Of Actual Infringement" with the Patent Office in connection with six pending Wright and Falotico patent applications. (D.I. 41, J&J Amended Motion to Dismiss at 13.) In the Original Delaware Complaint, Abbott explained how J&J asked the Patent Office to expedite its review of the related, but still pending, Wright and Falotico patent applications based on its counsel's assertions (1) that XIENCE V "unquestionably" infringes the claims of the Wright and Falotico patent applications and (2) that J&J could sue Abbott for infringement immediately upon issuance of those applications. (*Id.*, ¶¶ 41, 45.) The Original Delaware Complaint further described how the claimed subject matter in the pending applications overlapped with that in the Wright and Falotico patents-in-suit.[2] (*Id.*, ¶¶ 42,

[2] As is evident from the prosecution history, claims of the Wright 286 patent are very similar to claims of the Wright and Falotico patents-in-suit. For example, during the prosecution of the Wright 286 patent, the Patent Office expressly determined that claims of the Wright 286 patent are "not patentably distinct" from claims of the Wright 764 patent-in-suit. (*See, e.g.*, Ex. 7, Office Action at ABT 8786.) J&J filed "terminal

46.) Though Abbott could not yet seek declaratory judgment relief on the unissued Wright and Falotico patent applications, the Original Delaware Complaint expressly raised the fact that, due to J&J's threatening statements, a declaratory judgment lawsuit on these patent applications was imminent. Indeed, after discussing the pending applications, the Complaint expressly alleged that "J&J is preparing to assert one or more patents in the Wright family, including at least the Wright '764 patent and the Wright '536 patent, against the XIENCE V following its imminent launch."[3] (*Id.*, ¶ 43; *see also id.*, ¶ 47.)

On December 13, 2006, J&J filed a motion to dismiss the Original Delaware Complaint for lack of subject matter jurisdiction, claiming that Abbott did not have a reasonable apprehension of suit. (D.I. 14.) J&J addressed the pending Wright and Falotico patent applications in its motion. J&J attempted to dismiss the statements it made during prosecution, asserting that its infringement allegations were not threatening because J&J "merely [stated] that it 'could' assert some [Wright and Falotico] claims if they ultimately issued." (*Id.* at 12, 23.) In late April 2007, J&J filed an amended memorandum in support of its motion to dismiss in view of the fact that recent Supreme

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disclaimers" so that the Wright 286 patent expires at the same time as the Wright 764 patent-in-suit (in addition to other related patents and patent applications). (*See, e.g.*, Ex. 7, Terminal Disclaimers.)

[3] Because the pending Wright and Falotico patent applications are so closely related to the Wright and Falotico patents-in-suit and because of the overlapping subject matter, J&J's express infringement allegations on the patent applications were not only threatening as to those applications, but also as to the issued patents-in-suit. *See, e.g.*, *Champion, Int'l, Inc. v. Tech. Dev. Corp.*, 24 U.S.P.Q.2d 1077, 1078 (S.D. Ohio 1992); *Smithkline Beecham Corp. v. Zenith Goldline Pharms., Inc.*, No. 00-CV-1393, 2000 U.S. Dist. LEXIS 9659 at *5 (E.D. Penn. June 28, 2000).

Court and Federal Circuit case law eliminated the "reasonable apprehension" standard, lowering the threshold for establishing subject matter jurisdiction in a declaratory judgment case. (D.I. 41.) J&J's second motion again addressed the pending Wright and Falotico patent applications, some of which were now perilously close to issuing (as discussed below). (*Id* at 13-14, 21-22.) Acknowledging that it had filed six Petitions to Make Special Because of Actual Infringement, J&J again addressed, but cursorily dismissed, its express infringement charges against XIENCE V. (*Id* at 13.) In short, as is evident from the papers filed by both Plaintiffs and Defendants, the pending Wright and Falotico patent applications were not only implicated by, but intimately involved in, the present lawsuit filed by Abbott in September 2006.

C. Abbott's Motion To Supplement The Original Delaware Complaint And Abbott's Second Delaware Complaint For Declaratory Judgment

In late April and early May 2007, the Patent Office sent notice that two new patents would issue, on May 15 and May 29, from applications in the Wright family that had received expedited review due to J&J's "Petitions to Make Special Because of Actual Infringement." (Ex. 1, Issue Notifications.) On May 14, 2007, Abbott contacted J&J to determine whether J&J would stipulate to adding the new Wright patents to the present action in this Court because the patents are directly related, the parties are the same, and the allegedly infringing product is the same:

> We are aware that U.S. Patent No. 7,217,286 will issue tomorrow (May 15) from application no. 11/467,035 and U.S. Patent No. 7,223,286 will issue on May 29 from application no. 10/951,385. Please let us know today whether J&J will stipulate that Abbott may either (1) supplement the complaint to add a declaratory judgment claim for each of the new patents or (2) consolidate the present action with new declaratory judgment complaints for each of the new patents.

(Ex. 2, 5/14/07 Hansen email.) J&J flatly refused. (Ex. 3, 5/14/07 Cass email.)

On May 15, 2007, the Patent Office issued the Wright 286 patent. (Ex. 5.) That same day, immediately after midnight Eastern time, Plaintiffs moved for leave to supplement the Original Delaware Complaint to add a declaratory judgment claim for the Wright 286 patent given the interrelatedness of the patents, parties, and accused product. (Ex. 8, Notice of Electronic Filing; D.I. 43.) As soon as the clerk's office opened at 8:30 a.m., Plaintiffs also filed a second complaint in this Court seeking a declaratory judgment that the Wright 286 patent is invalid and not infringed by Plaintiffs ("the Second Delaware Complaint").[4] (*See* Ex. 9, time-stamped documents; D.I. 1, Civ. No. 07-259.) In the alternative, Abbott moved for consolidation of the original Delaware action with the second Delaware action.[5]

D. Cordis' Later-Filed New Jersey Lawsuit

Unbeknownst to Abbott, after receiving Abbott's email about supplementing the Original Delaware Complaint, Defendant Cordis filed its own complaint for infringement of the Wright 286 patent in the District of New Jersey.[6] (Ex. 10, Notice of Electronic Filing and Complaint.) According to the Notice of Electronic Filing received from the court in New Jersey, Cordis' New Jersey Complaint was entered on the docket at 11:07

[4] Moreover, the Second Delaware Complaint was also submitted as Exhibit 2 in support of Abbott's motion to supplement or consolidate, filed at 12:01 a.m. on May 15, 2007. (D.I. 44 at Ex. 2.) As will be explained below, Cordis' New Jersey Complaint subsequently was filed more than two hours later at 11:07 a.m.

[5] Abbott also requested that the Court deem both the supplemental complaint and the new complaint filed as of the time of filing the motion to supplement. (D.I. 44 at 6, 8.)

[6] Defendant Johnson and Johnson and Plaintiff Abbott Cardiovascular Systems, Inc. were not named parties in Cordis' New Jersey Complaint. (*See* Ex. 10.)

a.m. on May 15, 2007 – after Abbott had moved to supplement the Original Delaware Complaint and after Abbott filed its Second Delaware Complaint.[7] (*Id.* at Notice of Electronic Filing.) In the New Jersey Complaint, Cordis alleges that Abbott Laboratories is infringing the Wright 286 patent by "making and/or using the XIENCE V stent in the United States," an issue already raised by Plaintiffs in this Court. (*Id.* at Compl., ¶ 8.)

III. THE COURT SHOULD ENJOIN CORDIS FROM PURSUING ITS NEW JERSEY LAWSUIT UNDER THE "FIRST-TO-FILE" RULE

A. Under Well-Established Precedent, The First Litigant Enjoys A "Presumptive Right" To Choose The Forum

In patent cases, the Federal Circuit applies the well-established "general rule" that "the forum of the first-filed case is favored" unless there is "sound reason that would make it unjust or inefficient to continue the first-filed action." *Genentech, Inc. v. Eli Lilly and Co.*, 998 F.2d 931, 937-38 (Fed. Cir. 1993); *see also Electronics for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1348 (Fed. Cir. 2005). Importantly, "[t]he general rule favors the forum of the first-filed action, whether or not it is a declaratory action." *Genentech*, 998 F.2d at 937. "While the first-filed rule 'is not a rigid or inflexible rule to be mechanically applied, only in rare or extraordinary circumstances should the first-filed action give way

[7] Under the local rules in New Jersey, a document filed electronically "is deemed filed on the date and time stated on the Notice of Electronic filing from the court." (*See, e.g.*, Ex. 13, excerpts of New Jersey Local Rule 5.2(6) at 6.) Abbott repeatedly asked Defendants for a copy of the Notice of Electronic Filing for the New Jersey Complaint. (*See, e.g.*, Ex. 12, 5/15/07 and 5/16/07 Hansen emails.) Defendants, however, ignored Abbott's requests and never provided a copy. Moreover, contrary to the recommendations in the local rules in New Jersey, Cordis did not include a copy of the Notice of Electronic Filing with the summons for the New Jersey Complaint. Abbott was forced to obtain the Notice attached as Exhibit 10 from the court in New Jersey. (Ex. 10, Notice of Electronic Filing.)

to one filed later." *Chase Manhattan Bank, USA v. Freedom Card, Inc.*, 265 F. Supp. 2d 445, 448 (D. Del. 2003) (emphasis added) (internal quotations and citations omitted) *quoting in part EEOC v. University of Pa.*, 850 F.2d 969, 971 (3d Cir. 1988). "Such circumstances include inequitable conduct, bad faith, or forum shopping." *Id.* (internal quotations omitted); *see also Genentech*, 998 F.2d at 938 (also considering, *inter alia,* possibility of consolidation with related litigation and convenience and availability of witnesses). Simply put, the "presumptive right of the first litigant to choose the forum weigh[s] heavily in [that litigant's] favor" and that right should be disturbed "only to prevent wrong or injustice." *Kahn v. General Motors Corp.*, 889 F.2d 1078, 1082, 1081 (Fed. Cir. 1989) (emphasis added).

Noting the importance of the first-to-file rule, this Court has explained the sound principles that underlie the rule:

> The policy underlying that rule is at least two fold and eminently practical. For the benefit of litigants, 'the party who first brings a controversy into a court of competent jurisdiction for adjudication should...be free from the vexation of subsequent litigation over the same subject matter.' [citation omitted]. For the benefit of courts and the public they serve, 'courts already heavily burdened with litigation with which they must of necessity deal should...not be called upon to duplicate each other's work involving the same issues and the same parties.'

Chase, 265 F. Supp. 2d at 448 *quoting Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925 (3d Cir. 1941).

In view of the deeply-rooted general rule favoring the first-filed forum and "[t]he economic waste involved in duplicating litigation," it is well settled that "a United States district court which first obtains jurisdiction of the parties and issues may...enjoin proceedings involving the same issues and parties begun thereafter in another United

States district court." *Crosley*, 122 F.2d at 927, 930; *Thales Airborne Sys. S.A. v. Universal Avionics Sys. Corp.*, Civ. No. 05-853-SLR, 2006 U.S. Dist. LEXIS 41895, at *9 (D. Del. June 21, 2006) (citing *Crosley*); *see also Kerotest Mfg. Co. v. C-O-Two Fire Equip. Co.*, 342 U.S. 180, 185-86 (1952).

B. Cordis Is Not Entitled To Proceed In Its Later-Filed New Jersey Lawsuit

1. Because The September 2006 Delaware Action Is The First-Filed Action, Abbott Has A "Presumptive Right" To The Delaware Forum

Under well-established case law, Delaware is the favored forum because Abbott's Original Delaware Complaint, filed in September 2006, commenced the first-filed action. Courts have consistently held that the first-filed forum is where the parties originally sued each other, even if the parties later raise additional or new claims in subsequently-filed lawsuits on related subject matter. *See, e.g., Mattel, Inc. v. Louis Marx & Co.*, 353 F.2d 421, 424 (2d Cir. 1965); *Kerotest*, 342 U.S. at 181-182 (favoring first-filed forum even when second-filed case added new parties). In particular, courts have routinely held that, if parties are involved in a lawsuit regarding patent rights in one forum and one of the parties later files a second action in another forum on a newly-issued and related patent, the original forum is the first-filed (and favored) forum. For example, in *Cosden Oil & Chem. Co. v. Foster Grant Co.*, 432 F. Supp. 956, 957-58 (D. Del. 1977), plaintiff Cosden filed a declaratory judgment action in Delaware against the patentee Foster for noninfringement and invalidity of a patent. Later, a second patent, which was related to the first patent, issued. *Id.* On the day the second patent issued, Foster filed a complaint in Texas for infringement of that patent. *Id.* at 958. Three days later, Cosden filed an

amended complaint in Delaware seeking a declaratory judgment that the second patent was invalid and not infringed. *Id.* Cosden moved to enjoin the prosecution of the Texas lawsuit. *Id.* Applying the first-to-file rule, the Delaware court granted Cosden's motion to enjoin:

> The similarity between the [original] '434 patent and the [newly-issued] '311 patent and the intimate relationship between the respective file histories of these two patents leaves no question in my mind that the controversy surrounding the '311 patent is part and parcel of the controversy surrounding the '434 patent. As such, under the first-filed doctrine enunciated by the Third Circuit Court of Appeals in *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925 (3rd Cir. 1941), I have no choice but to enjoin the Dallas suit pending disposition of the claims here. Cosden is entitled to be free from the 'vexation of subsequent litigation over the same subject matter' 122 F.2d at 930, and the courts are entitled to be free from the waste and inefficiency involved in duplicative litigation.

Id. at 960 (emphasis added).

Likewise, in *Intel Corp. v. AmberWave Sys. Corp.*, 233 F.R.D. 416 (D. Del. 2005), the Delaware court favored the first-filed Delaware forum when faced with a race to the courthouse on newly-issued patents. There, like here, Intel filed a declaratory judgment complaint in Delaware relating to one patent and mentioned certain other pending patent applications in its complaint. *Id.* at 416-17. In the *Intel* case, the pending patent applications involved the same technology as the patent-in-suit, as in the present case, but, unlike this case, were not from the same patent family as the original patent. (*Id.*) At 5:50 a.m. CST, on the day the first of the pending applications issued, the patentee AmberWave left an infringement complaint in a drop box at a federal courthouse in Texas. *Id.* at 417. Less than two hours later, at 8:30 a.m. EST, Intel filed a complaint for declaratory judgment of noninfringement in Delaware. *Id.* Six days later,

Intel filed a motion to supplement its complaint by adding its declaratory judgment claims. *Id.* Considering principles of judicial economy, the court recognized that the original Delaware action was the first-filed action and granted Intel's motion to supplement:

> The more sensible view must acknowledge that, at a minimum, presentations on infringement for both the [original] '292 patent and the [newly-issued] '371 patents will require a judge, on the summary judgment motions that are sure to be filed, and a jury, at any trial of the case, to become familiar with the same field of art, the same fundamental science and technology associated with methods of semiconductor fabrication, the same allegedly infringing devices, and, in any damages analysis, the same pricing, sales, and related market data....[I]t is highly likely that the same or substantially overlapping operative facts regarding Intel's decision-making and AmberWave's negotiations with Intel will also be at issue with regard to both patents....[T]here is substantial overlap of core issues with respect to the alleged infringement of both the '371 and the '292 patents.
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> ...I am persuaded that, at least for purposes of determining the priority of litigation between this court and the Eastern District of Texas in this case, it is appropriate to consider this the first-filed action. By AmberWave's own reasoning [citation omitted], the court with the first-filed action should determine where the parties' dispute over the [newly-issued] '371 patent should be resolved. For the reasons outlined, I have decided that this court is the more appropriate forum....I will already be dealing with the [original] '292 and the '632 patents. It makes no sense to burden the Eastern District of Texas with this third and latest version of the substantially overlapping disputes between the parties.

Id. at 418-19 (emphasis added). In the present action, the case for enjoining Cordis from pursuing the New Jersey Complaint is even stronger because (1) the respective patents are directly related and claim subject matter that the Patent Office determined is "not patentably distinct;" and (2) Abbott filed the Second Delaware Complaint and its motion to supplement before the Cordis New Jersey Complaint was filed.

In yet another example, *Hooker Chems. & Plastics Corp. v. Diamond Shamrock Corp.*, 87 F.R.D. 398 (W.D.N.Y. 1980), Hooker filed a declaratory judgment action against Diamond relating to certain patents in the Western District of New York. *Id.* at 400. The Patent Office later issued a related patent to Diamond. *Id.* In an attempt to avoid the New York forum selected by Hooker, Diamond filed a patent infringement lawsuit on its newly-issued patent in Oklahoma. *Id.* Several weeks later, Hooker amended its New York complaint to add a declaratory judgment count relating to the newly-issued patent. *Id.* The court enjoined Diamond from proceeding with its second-filed Oklahoma action:

> It is undoubtedly true that Hooker would have included the March 11, 1980 '725 patent in the original complaint if it had been issued on September 26, 1979 when this litigation began. The [newly-issued] '725 patent is itself denominated a "continuation" of the [original] '405 patent. Both concern the same technology. Both arose from a common application filed in 1971. Both contain claims which are very similar, if not completely identical....In short, I find Hooker's "Second Amended Complaint" to be "part and parcel" of the same controversy as the original complaint, and therefore, entitled to relation back under Rule 15(c).

Id. at 403 (citations omitted).[8]

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[8] *See also Owens-Illinois Glass Container, Inc. v. B&H Mfg., Inc.*, 13 U.S.P.Q.2d 2061, 2062, 2064 (E.D. Cal. 1989) (using first-to-file rule to transfer case relating to newly-issued patent to N.D. Ga. where case on related patent was already pending); *Applied Vision, Inc. v. Optical Coating Lab, Inc.*, No. C97-1233, 1997 U.S. Dist. LEXIS 16306, at *13 (N.D. Cal. Sept. 23, 1997) (holding that a previously filed complaint on a different patent was the first-filed lawsuit as "the technology, parties and circumstances surrounding the patents in question are similar enough to be considered to share a common core of operative facts"); *Saes Getters v. Aeronex, Inc.*, 219 F. Supp. 2d. 1081, 1090 (S.D. Cal. 2002) ("a number of courts have concluded that the first-filed forum is the one in which the parties originally were brought, not the one in which the precise issue was first raised. In other words, the forum with priority is the one where the parties initially sued each other, even if the parties raise a different claim in a subsequently filed suit in a different forum."); *Versus Tech., Inc. v. Hillenbrand Indus.*,

The rule favoring the original first-filed case between the parties promotes the policy underlying the first-to-file rule. In *Kimberly-Clark Corp. v. McNeil-PPC, Inc.*, 260 F. Supp. 2d. 738 (E.D. Wis. 2003), McNeil sought a declaratory judgment as to one of Kimberly-Clark's patents, the Romans-Hess patent, in New Jersey. *Id.* at 739. One week later, Kimberly-Clark filed a patent infringement action in Wisconsin, alleging that McNeil infringed two additional patents. *Id.* at 738-39. Upon learning of the Wisconsin lawsuit, McNeil amended its declaratory judgment complaint to include all three patents. *Id.* Kimberly-Clark attempted to argue that McNeil's New Jersey lawsuit was the first-filed case only as to the Romans-Hess patent, and that its Wisconsin lawsuit was the first-filed case as to the other patents. *Id.* at 739. Following the general rule regarding "first-to-file" and staying the Wisconsin case, the Wisconsin court underscored the policies underlying the first-filed rule and highlighted the potential for gamesmanship absent the rule:

> The issue, however, is not which of the claims was filed first, but rather which action was filed first....If, as [Kimberly-Clark's] argument implies, each court were to determine as to each claim in the action before it whether it was filed first and whether to allow it to proceed in this court, it would unduly complicate what should be a purely procedural threshold issue....Furthermore, accepting such a distinction would sanction additional procedural fencing. For example, if the second-filed party wanted to defeat the first-filed rule under similar circumstances, it need

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Inc., No. 1:04-CV-168, 2004 U.S. Dist. LEXIS 28331, at *17 (W.D. Mich. Nov. 23, 2004) (holding that "[a]lthough Versus is correct that its claims were first raised in this case, several courts have held that a subsequently-filed amendment is prior to an earlier complaint where the amendment is made in the first-filed action") (internal citations omitted); *Ramsey Grp., Inc. v. EGS Int'l, Inc.*, 208 F.R.D. 559, 563 (W.D.N.C. 2002) (holding that the amendment to add a newly issued patent relates back to the original complaint because the patents were related and the cases involve the same parties, products and technology).

> only add an additional claim to its complaint, i.e. a claim not present in the other party's first-filed action. It would then be able to argue that its new claim should be considered separately from any claims filed by the other side. This would lead to disjointed litigation and would thwart any semblance of judicial economy or efficiency.

Id. at 740-41.

In this case, Abbott's Original Delaware Complaint, filed in September 2006, was the first action to raise the noninfringement and invalidity issues surrounding the Wright and Falotico patent families and Abbott's XIENCE V drug-eluting stent system. (D.I. 1, Compl.) Indeed, Abbott even raised the pending Wright and Falotico patent applications, and J&J's threatening conduct relating to those applications, in the Original Delaware Complaint. (*Id* at ¶¶ 40-47.) Moreover, Abbott advised Cordis, in advance, that Abbott was planning to supplement the Original Delaware Complaint to add declaratory judgment claims relating to the Wright 286 patent. Acting without delay, immediately after midnight on May 15, 2007, the day the Wright 286 patent issued, Abbott did in fact move to supplement – just as it had advised Cordis. Shortly after midnight, Cordis received Abbott's motion and a copy of Abbott's Second Delaware Complaint. (Ex. 8, Notice of Electronic Filing.) Abbott also separately filed the Second Delaware Complaint regarding the Wright 286 patent at 8:30 a.m. that same day – the earliest possible time in Delaware. (Ex. 9.) Abbott took all of these steps before Cordis' New Jersey Complaint raising the same issues was filed at 11:07 a.m. (Ex. 10.) Accordingly, the present action in this Court is the first-filed action and Delaware is the favored forum.

Moreover, even if the Court did not consider Abbott's Original Delaware Complaint or Abbott's motion to supplement that Complaint, Delaware is still the

favored forum. In other words, even if only Abbott's Second Delaware Complaint and Cordis' New Jersey Complaint were considered, Abbott nevertheless is the first to file an independent action addressing the invalidity and noninfringement of the Wright 286 patent. Abbott's Second Delaware Complaint was filed at 8:30 a.m.[9] (Ex. 9.) On the other hand, Cordis' New Jersey Complaint was filed more than two hours later at 11:07 a.m. (Ex. 10.) Courts have held that, even when complaints are filed within hours of each other, the first-to-file rule still applies to favor the first forum. *See Laboratory Corp. v Chiron Corp.*, 384 F.3d 1326, 1332 (Fed. Cir. 2004) (district court did not err in applying the first-to-file rule to enjoin other court where parties filings were four hours apart); *Matsushita Battery Indus. Co., v. Energy Conversion Devices, Inc.*, No. 96-101-SLR, 1996 U.S. Dist. LEXIS 8153, at *2 (D. Del. Apr. 23, 1996) (granting plaintiffs' motion to enjoin where defendants filed suit in another forum the day after plaintiffs filed suit in Delaware); *Chase*, 265 F. Supp. at 446 (granting plaintiff's motion to enjoin where second-filed action was filed 1½ hours after the filing of Delaware action).

In summary, before Cordis' New Jersey Complaint was filed, Abbott filed the Original Delaware Complaint, addressing invalidity and noninfringement of the Wright and Falotico patent families, and filed the Second Delaware Complaint, addressing invalidity and noninfringement of the newly-issued Wright 286 patent. Accordingly, Abbott has a "presumptive right" to proceed in this Court, the forum Abbott selected and

[9] Moreover, well before 8:30 a.m., Abbott filed a copy of its Complaint as Exhibit 2 in support of its motion to supplement or consolidate and, in that motion, Abbott requested the Court to deem the Second Delaware Complaint filed as of the filing of Abbott's motion. (D.I. 44 at 8; *id.* at Ex. 2.)

a forum that has substantial experience with the parties and with patent litigation relating to stents for coronary angioplasty.

2. Cordis Cannot Establish That Proceeding In Delaware Would Result In "Wrong Or Injustice"

As discussed above, Abbott's "presumptive right...to choose the forum weigh[s] heavily in [Abbott's] favor" and should be disturbed "only to prevent wrong or injustice." *Kahn*, 889 F.2d at 1082, 1081. J&J cannot establish that Abbott had no "sound reason" for filing its suit in Delaware or that Abbott's choice "was motivated by inequitable conduct, bad faith, or forum shopping." *Genentech*, 998 F.2d at 938 (district court abused its discretion in dismissing first-filed action in favor of a second-filed action filed a day later in the patentee's home state because declaratory judgment plaintiff had "sound reason" for choosing its forum); *Chase*, 265 F. Supp. at 448.

Not only does the first-to-file rule favor Delaware, but Delaware is the most convenient forum for this particular case. Notably, Cordis has initiated numerous lawsuits in Delaware over the years. In fact, as was alleged in the Original Delaware Complaint, Cordis has found Delaware particularly convenient for litigating patent cases involving angioplasty catheters and stents for treating coronary artery disease. (D.I. 1, Compl., ¶ 3.) For example, considering just the narrow field of angioplasty catheters and stents, Cordis has found Delaware to be the best forum six times in the last ten years.[10] In

[10] *See Cordis Corp., et al. v. Advanced Cardiovascular Sys., Inc, et al.*, C.A. No. 97-550-SLR; *Cordis Corp., et al. v. Advanced Cardiovascular Sys., Inc., et al.*, C.A. No. 97-635-SLR; *Cordis Corp., et al. v. Advanced Cardiovascular Sys., Inc., et al.*, C.A. No. 98-065-SLR; *Cordis Corp. v. Boston Scientific Corp.*, C.A. No. 98-197-SLR; *Cordis Corp. v. Medtronic AVE, Inc.*, C.A. No. 00-886-SLR; and *Cordis Corp. v Boston Scientific Corp.*, C.A. No. 03-027-SLR.

fact, Delaware is so convenient for Cordis, it recently moved to transfer a case pending in the Eastern District of Texas to Delaware. (Ex. 14, Docket Sheet, Entry Nos. 64 and 66.)

Moreover, because of the extensive history of stent-related litigation in Delaware, Delaware is a superior forum for this particular case. The Court is already familiar with the parties, stents for coronary angioplasty, and the types of issues that will arise in this case. *See Genentech*, 998 F.2d at 938 ("sound reason" existed for plaintiff's forum choice where plaintiff "sought consolidation with suits already pending in [that forum]"); *Ellis Corp. v. Jensen USA, Inc.*, No. 02-C-7380, 2003 U.S. Dist. LEXIS 15811, at * 11 (N.D. Ill. Sept. 9, 2003) (transferring case to judicial district where "court is more familiar with the parties and the salient issues of the case"); *Optical Recording Corp v Capitol-EMI Music, Inc.*, 803 F. Supp. 971, 973-74 (D. Del. 1992) (court's familiarity with the relevant technology and patents was of such importance to judicial economy that it justified a departure from the first-to-file rule); *Fox News Networks, L.L.C. v. Time Warner, Inc.*, No. 96-CV-493, 1997 U.S. Dist. LEXIS 6940, at *8-10 (E.D.N.Y. May 16, 1997) (transferring to SDNY because it was familiar with the case's background based on related case pending there).

Despite its repeated selection of Delaware as the most convenient forum, Cordis will likely argue that New Jersey is a better forum because its "principal place of business [is] in Warren, New Jersey." (*See* Ex. 10, Cordis New Jersey Complaint, ¶ 1.) This argument fails for at least three reasons.

First, even if Cordis has a principal place of business in New Jersey, Abbott nevertheless has a presumptive right to the Delaware forum. *Padcom, Inc. v NetMotion*

Wireless, Inc., No. 03-983-SLR, 2004 U.S. Dist. LEXIS 9658, at *3, 20-25 (D. Del. May 24, 2004) ("consistent with the deference afforded a plaintiff's choice of forum," refusing to transfer case to Washington, where one of the defendants was incorporated and had its principal place of business, because defendant "is a company trying to conduct business on a nationwide basis, including Delaware").

Second, contrary to Cordis' present allegation in its New Jersey Complaint, Cordis previously denied that it has a principal place of business in New Jersey. More specifically, in December 2006, in direct conflict with its recently-filed New Jersey Complaint, Cordis filed an Answer in another case pending in Texas denying that it had a principal place of business in New Jersey, and claiming that it had a principal place of business in Florida. (Ex. 15, excerpts from Complaint and Answer, ¶ 3.)

Third, even if Cordis now wants to claim a home in New Jersey, New Jersey is no more convenient than Delaware. The Trenton courthouse – where Cordis wants to litigate over the Wright 286 patent – is only about one hour away from this Court. *See, e.g., Chase,* 265 F. Supp. 2d at 451 (defendant unable to show that witnesses would be inconvenienced "by the relatively short trip from New York City to Wilmington"); *Spotless Enters. Inc. v. Accessory Corp.*, 415 F. Supp. 2d 203, (E.D.N.Y. 2006) (EDNY no more convenient than SDNY); *Saes,* 219 F. Supp. 2d at 1092-93 (the 120 mile distance between the S.D. Cal. and C.D. Cal. was "simply not great enough to persuade the Court that the Southern District is an inconvenient forum.").

In sum, J&J simply cannot establish that Delaware would be an unjust forum. Not only does the first-to-file rule favor Delaware, but judicial economy favors keeping

the dispute surrounding the Wright 286 patent in Delaware – where the Original Delaware Complaint involving the same parties, the same family of patents, and the same accused product is already pending and where this Court is uniquely familiar with patent lawsuits involving stents and these parties.

IV. CONCLUSION

The first-to-file rule favors the Delaware forum and Delaware is the best forum for this case. For the aforementioned reasons, Abbott respectfully requests that this Court enjoin Cordis from prosecuting its complaint in New Jersey.

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Date: May 18, 2007

CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2007 caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

Steven J. Balick, Esquire
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I hereby certify that on May 18, 2007, I caused to be sent by Federal Express the foregoing document to the following non-registered participant:

David T. Pritikin, Esquire
William H. Baumgartner, Jr., Esquire
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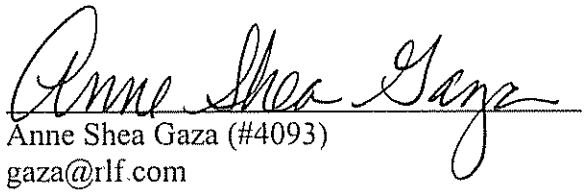

Anne Shea Gaza (#4093)
gaza@rlf.com

Exhibit 1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/467,035	05/15/2007	7217286	CRDS-0067	2954

45511 7590 04/25/2007

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

ROBERT FALOTICO, BELL MEAD, NJ;
Gerard H. Llanos, Stewartsville, NJ;

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/951,385	05/29/2007	7223286	JJI-51-CON2	7537

27777 7590 05/09/2007

PHILIP S. JOHNSON
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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 265 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

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Ronald Rakos, Neshanic Station, NJ;
Kristin King, Mahwah, NJ;
Robert Falotico, Bell Mead, NJ;

Exhibit 2

From: Leland Hansen
Sent: Monday, May 14, 2007 4:48 PM
To: 'pveith@Sidley.com'
Cc: 'dpritikin@sidley.com'; 'rcass@Sidley.com'
Subject: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Paul:

I am writing to follow up on my prior voicemail. I have tried to call you several times but each time I have been immediately directed to your voicemail.

We are aware that U.S. Patent No. 7,217,286 will issue tomorrow (May 15) from application no. 11/467,035 and U.S. Patent No. 7,223,286 will issue on May 29 from application no. 10/951,385. Please let us know today whether J&J will stipulate that Abbott may either (1) supplement the complaint to add a declaratory judgment claim for each of the new patents or (2) consolidate the present action with new declaratory judgment complaints for each of the new patents.

Also, please let us know today whether J&J will withdraw its motion to dismiss.

Leland

Leland G. Hansen
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Exhibit 3

From: Leland Hansen
Sent: Tuesday, May 15, 2007 10:18 AM
To: 'rcass@Sidley.com'
Cc: dpritikin@sidley.com; pveith@Sidley.com
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Russ:

Because J&J would not stipulate, we have filed a Complaint For Declaratory Judgment Of Patent Invalidity And Noninfringement for U.S. Patent No. 7,217,286 (the Falotico 286 patent). I have attached courtesy copies of the complaint and related documents.

Also, we filed a Motion For Leave To File A Supplemental Complaint Or In The Alternative To Consolidate Related Actions. The motion and related documents were served previously.

If J&J or Cordis has filed or files a complaint for the Falotico 286 patent, the Wright 764 patent, the Wright 536 patent, the Falotico 796 patent, or any related patent, please promptly provide us with courtesy copies.

Leland

From: rcass@Sidley.com [mailto:rcass@Sidley.com]
Sent: Monday, May 14, 2007 6:07 PM
To: Leland Hansen
Cc: dpritikin@sidley.com; pveith@Sidley.com
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Leland:

Paul is out of town, so I am responding to your e-mail. We have contacted our client, and J&J does not consent to supplementing the complaint to add a new declaratory judgment claim or consolidating the present action with a new declaratory judgment complaint. J&J also will not be withdrawing its motion to dismiss.

Russ

From: LHANSEN@mcandrews-ip.com [mailto:LHANSEN@mcandrews-ip.com]
Sent: Monday, May 14, 2007 4:48 PM
To: Veith, Paul E.
Cc: Pritikin, David T.; Cass, Russell E.
Subject: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Paul:

I am writing to follow up on my prior voicemail. I have tried to call you several times but each time I have been immediately directed to your voicemail.

We are aware that U.S. Patent No. 7,217,286 will issue tomorrow (May 15) from application no. 11/467,035 and U.S. Patent No. 7,223,286 will issue on May 29 from application no. 10/951,385. Please let us know today whether J&J will stipulate that Abbott may either (1) supplement the complaint to add a declaratory judgment claim for each of the new patents or (2) consolidate the present action with new declaratory judgment complaints for each of the new patents.

Also, please let us know today whether J&J will withdraw its motion to dismiss.

Leland

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to by other parties in promoting, marketing or recommending any partnership or other entity,
investment plan or arrangement, then (i) the advice should be construed as written in connection
with the promotion or marketing by others of the transaction(s) or matter(s) addressed in this
communication and (ii) the taxpayer should seek advice based on the taxpayer's particular
circumstances from an independent tax advisor.

Exhibit 4

Not Used

Exhibit 5

US007217286B2

(12) **United States Patent**
Falotico et al.

(10) **Patent No.: US 7,217,286 B2**
(45) **Date of Patent: *May 15, 2007**

(54) **LOCAL DELIVERY OF RAPAMYCIN FOR TREATMENT OF PROLIFERATIVE SEQUELAE ASSOCIATED WITH PTCA PROCEDURES, INCLUDING DELIVERY USING A MODIFIED STENT**

(75) Inventors: **Robert Falotico**, Bell Mead, NJ (US); **Gerard H. Llanos**, Stewartsville, NJ (US)

(73) Assignee: **Cordis Corporation**, Miami Lakes, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/467,035**

(22) Filed: **Aug. 24, 2006**

(65) **Prior Publication Data**

US 2007/0021825 A1 Jan. 25, 2007

Related U.S. Application Data

(63) Continuation of application No. 10/951,385, filed on Sep. 28, 2004, which is a continuation of application No. 10/408,328, filed on Apr. 7, 2003, now Pat. No. 6,808,536, which is a continuation of application No. 09/874,117, filed on Jun. 4, 2001, now Pat. No. 6,585,764, which is a continuation of application No. 09/061,568, filed on Apr. 16, 1998, now Pat. No. 6,273,913.

(60) Provisional application No. 60/044,692, filed on Apr. 18, 1997.

(51) **Int. Cl.**
A61F 2/06 (2006.01)

(52) **U.S. Cl.** **623/1.42**

(58) **Field of Classification Search** 623/1.45–1.48; 427/2.1–2.31
See application file for complete search history.

(56) **References Cited**

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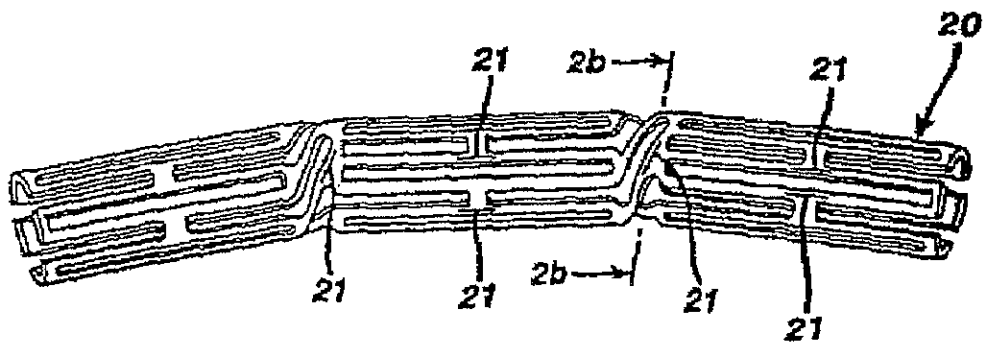
(Continued)

Primary Examiner—Suzette Gherbi
(74) *Attorney, Agent, or Firm*—Woodcock Washburn LLP

(57) **ABSTRACT**

Methods of preparing intravascular stents with a polymeric coating containing macrocyclic lactone (such as rapamycin or its analogs), stents and stent graphs with such coatings, and methods of treating a coronary artery with such devices. The macrocyclic lactone-based polymeric coating facilitates the performance of such devices in inhibiting restenosis.

5 Claims, 2 Drawing Sheets



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Jury verdict form from the *Cordis Corporation et al.* v. *Medtronic AVE, Inc. et al.* liability trial.

Hearing testimony trascript from the consolidated *Cordis Corporation et al.* v. *Medtronic AVE, Inc. et al.* and Boston Scientific Corporation et al. inequitable conduct hearing dated Feb. 7-9 and 12, 2001.

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Cordis Corporation v. *Advanced Cardiovascular Systems, Inc. et al.* (CA. No. 97-550-SLR), *Metronic AVE, Inc.* v. *Cordis Corporation et al.* (CA. No. 97-700-SLR), *Boston Scientific Corporation* v. *Athlcon, Inc. etal.* (CA. No. 98-19-SLR), Expert Report of John T. Goolkasian, Esq.

Cordis Corporation v. *Advanced Cardiovascular Systems, Inc. et al.* (CA. No. 97-550-SLR), *Medtronic A VE, Inc.* v. *Cordis Corporation et al* (CA. No. 97-700-SLR), *Boston Scientific Corporation* v. *Athlcon, Inc. et al* (CA. 98-19-SLR), Expert Report to John F. Witherspoon.

* cited by examiner

FIG. 1

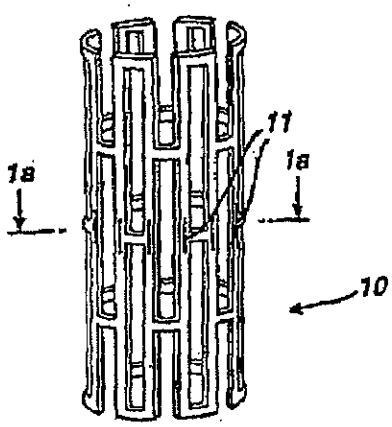


FIG. 1a

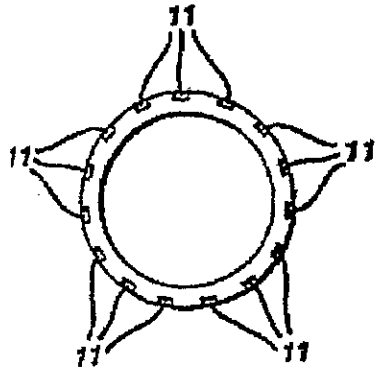


FIG. 2a

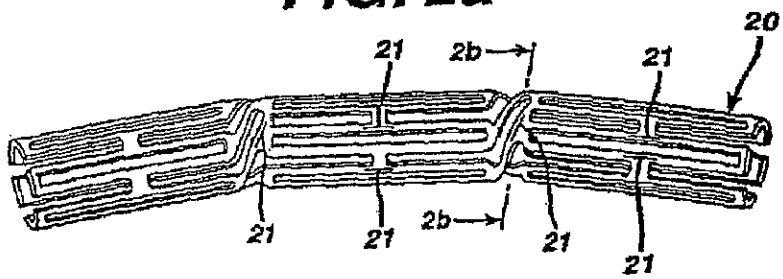


FIG. 2b

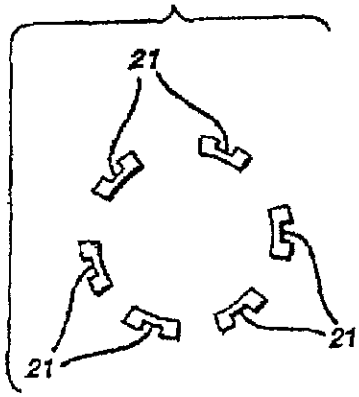


FIG. 3a

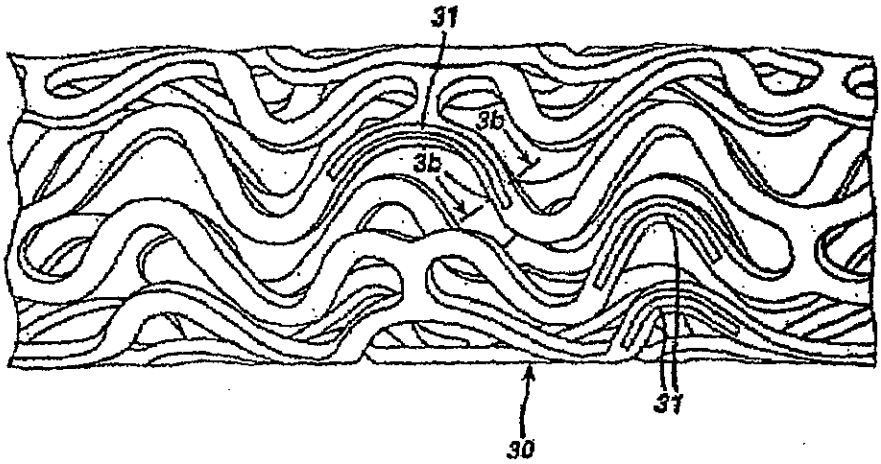


FIG. 3b

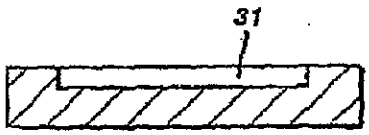
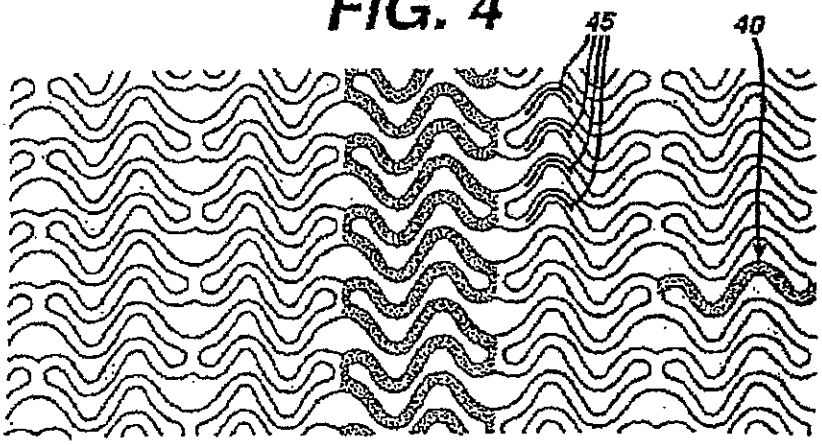


FIG. 4



LOCAL DELIVERY OF RAPAMYCIN FOR TREATMENT OF PROLIFERATIVE SEQUELAE ASSOCIATED WITH PTCA PROCEDURES, INCLUDING DELIVERY USING A MODIFIED STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of Ser. No. 10/951,385, filed Sep. 28, 2004, now pending, which in turn is a continuation of Ser. No. 10/408,328, filed Apr. 7, 2003, now issued as U.S. Pat. No. 6,808,536, which in turn is a continuation of application Ser. No. 09/874,117, filed Jun. 4, 2001, now issued as U.S. Pat. No. 6,585,764, which is a continuation of application Ser. No. 09/061,568, filed Apr. 16, 1998, now issued as U.S. Pat. No. 6,273,913, which in turn claims benefit of provisional application Ser. No. 60/044,692, filed Apr. 18, 1997. The disclosures of these prior applications are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

Delivery of rapamycin locally, particularly from an intravascular stent, directly from micropores in the stent body or mixed or bound to a polymer coating applied on stent, to inhibit neointimal tissue proliferation and thereby prevent restenosis. This invention also facilitates the performance of the stent in inhibiting restenosis.

BACKGROUND OF THE INVENTION

Re-narrowing (restenosis) of an artherosclerotic coronary artery after percutaneous transluminal coronary angioplasty (PTCA) occurs in 10–50% of patients undergoing this procedure and subsequently requires either further angioplasty or coronary artery bypass graft. While the exact hormonal and cellular processes promoting restenosis are still being determined, our present understanding is that the process of PTCA, besides opening the artherosclerotically obstructed artery, also injures resident coronary arterial smooth muscle cells (SMC). In response to this injury, adhering platelets, infiltrating macrophages, leukocytes, or the smooth muscle cells (SMC) themselves release cell derived growth factors with subsequent proliferation and migration of medial SMC through the internal elastic lamina to the area of the vessel intima. Further proliferation and hyperplasia of intimal SMC and, most significantly, production of large amounts of extracellular matrix over a period of 3–6 months results in the filling in and narrowing of the vascular space sufficient to significantly obstruct coronary blood flow.

Several recent experimental approaches to preventing SMC proliferation have shown promise although the mechanisms for most agents employed are still unclear. Heparin is the best known and characterized agent causing inhibition of SMC proliferation both in vitro and in animal models of balloon angioplasty-mediated injury. The mechanism of SMC inhibition with heparin is still not known but may be due to any or all of the following: 1) reduced expression of the growth regulatory protooncogenes c-fos and c-myc, 2) reduced cellular production of tissue plasminogen activator; are 3) binding and dequestration of growth regulatory factors such as fibrovalent growth factor (FGF).

Other agents which have demonstrated the ability to reduce myointimal thickening in animal models of balloon vascular injury are angiopeptin (a somatostatin analog), calcium channel blockers, angiotensin converting enzyme inhibitors (captopril, cilazapril), cyclosporin A, trapidil (an antianginal, antiplatelet agent), terbinafine (antifungal), colchicine and taxol (antitubulin antiproliferatives), and c-myc and c-myb antinsense oligonucleotides.

Additionally, a goat antibody to the SMC mitogen platelet derived growth factor (PDGF) has been shown to be effective in reducing myointimal thickening in a rat model of balloon angioplasty injury, thereby implicating PDGF directly in the etiology of restenosis. Thus, while no therapy has as yet proven successful clinically in preventing restenosis after angioplasty, the in vivo experimental success of several agents known to inhibit SMC growth suggests that these agents as a class have the capacity to prevent clinical restenosis and deserve careful evaluation in humans.

Coronary heart disease is the major cause of death in men over the age of 40 and in women over the age of fifty in the western world. Most coronary artery-related deaths are due to atherosclerosis. Atherosclerotic lesions which limit or obstruct coronary blood flow are the major cause of ischemic heart disease related mortality and result in 500,000–600,000 deaths in the United States annually. To arrest the disease process and prevent the more advanced disease states in which the cardiac muscle itself is compromised, direct intervention has been employed via percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG) PTCA is a procedure in which a small balloon-tipped catheter is passed down a narrowed coronary artery and then expanded to re-open the artery. It is currently performed in approximately 250,000–300,000 patients each year. The major advantage of this therapy is that patients in which the procedure is successful need not undergo the more invasive surgical procedure of coronary artery bypass graft. A major difficulty with PTCA is the problem of post-angioplasty closure of the vessel, both immediately after PTCA (acute reocclusion) and in the long term (restenosis).

The mechanism of acute reocclusion appears to involve several factors and may result from vascular recoil with resultant closure of the artery and/or deposition of blood platelets along the damaged length of the newly opened blood vessel followed by formation of a fibrin/red blood cell thrombus. Recently, intravascular stents have been examined as a means of preventing acute reclosure after PTCA.

Restenosis (chronic reclosure) after angioplasty is a more gradual process than acute reocclusion: 30% of patients with subtotal lesions and 50% of patients with chronic total lesions will go on to restenosis after angioplasty. While the exact mechanism for restenosis is still under active investigation, the general aspects of the restenosis process have been identified.

In the normal arterial will, smooth muscle cells (SMC) proliferate at a low rate (<0.1%/day; ref). SMC in vessel wall exists in a *contractile* phenotype characterized by 80–90% of the cell cytoplasmic volume occupied with the contractile apparatus. Endoplasmic reticulum, golgi bodies, and free ribosomes are few and located in the perinuclear region. Extracellular matrix surrounds SMC and is rich in heparin-like glycosylaminoglycans which are believed to be responsible for maintaining SMC in the contractile phenotypic state.

Upon pressure expansion of an intracoronary balloon catheter during angioplasty, smooth muscle cells within the arterial wall become injured. Cell derived growth factors such as platelet derived growth factor (PDGF), basic fibroblast growth factor (bFGF), epidermal growth factor (EGF),

etc. released from platelets (i.e., PDGF) adhering to the damaged arterial luminal surface, invading macrophages and/or leukocytes, or directly from SMC (i.e., BFGF) provoke a proliferation and migratory response in medial SMC. These cells undergo a phenotypic change from the contractile phenotype to a synthetic phenotype characterized by only few contractile filament bundles but extensive rough endoplasmic reticulum, golgi and free ribosomes. Proliferation/migration usually begins within 1–2 days post-injury and peaks at 2 days in the media, rapidly declining thereafter (Campbell et al., In: Vascular Smooth Muscle Cells in Culture, Campbell, J. H. and Campbell, G. R., Eds, CRC Press, Boca.Ratioh, 1987, pp. 39–55); Clowes, A. W. and Schwartz, S. M., Circ. Res. 56:139–145, 1985).

Finally, daughter synthetic cells migrate to the intimal layer of arterial smooth muscle and continue to proliferate. Proliferation and migration continues until the damaged luminal endothelial layer regenerates at which time proliferation ceases within the intima, usually within 7–14 days postinjury. The remaining increase in intimal thickening which occurs over the next 3–6 months is due to an increase in extracellular matrix rather than cell number. Thus, SMC migration and proliferation is an acute response to vessel injury while intimal hyperplasia is a more chronic response. (Liu et al., Circulation, 79:1374–1387, 1989).

Patients with symptomatic reocclusion require either repeat PTCA or CABG. Because 30–50% of patients undergoing PTCA will experience restenosis, restenosis has clearly limited the success of PTCA as a therapeutic approach to coronary artery disease. Because SMC proliferation and migration are intimately involved with the pathophysiological response to arterial injury, prevention of SMC proliferation and migration represents a target for pharmacological intervention in the prevention of restenosis.

SUMMARY OF THE INVENTION

Novel Features and Applications to Stent Technology Currently, attempts to improve the clinical performance of stents have involved some variation of either applying a coating to the metal, attaching a covering or membrane, or embedding material on the surface via ion bombardment. A stent designed to include reservoirs is a new approach which offers several important advantages over existing technologies.

Local Drug Delivery from a Stent to Inhibit Restenosis

In this application, it is desired to deliver a therapeutic agent to the site of arterial injury. The conventional approach has been to incorporate the therapeutic agent into a polymer material which is then coated on the stent. The ideal coating material must be able to adhere strongly to the metal stent both before and after expansion, be capable of retaining the drug at a sufficient load level to obtain the required dose, be able to release the drug in a controlled way over a period of several weeks, and be as thin as possible so as to minimize the increase in profile. In addition, the coating material should not contribute to any adverse response by the body (i.e., should be non-thrombogenic, non-inflammatory, etc.). To date, the ideal coating material has not been developed for this application.

An alternative would be to design the stent to contain reservoirs which could be loaded with the drug. A coating or membrane of biocompatable material could be applied over the reservoirs which would control the diffusion of the drug from the reservoirs to the artery wall.

One advantage of this system is that the properties of the coating can be optimized for achieving superior biocompatibility and adhesion properties, without the addition requirement of being able to load and release the drug. The size, shape, position, and number of reservoirs can be used to control the amount of drug, and therefore the dose delivered.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood in connection with the following figures in which FIGS. **1** and **1A** are top views and section views of a stent containing reservoirs as described in the present invention;

FIGS. **2***a* and **2***b* are similar views of an alternate embodiment of the stent with open ends;

FIGS. **3***a* and **3***b* are further alternate figures of a device containing a grooved reservoir; and

FIG. **4** is a layout view of a device containing a reservoir as in FIG. **3**.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Pharmacological attempts to prevent restenosis by pharmacologic means have thus far been unsuccessful and all involve systemic administration of the trial agents. Neither aspirin-dipyridamole, ticlopidine, acute heparin administration, chronic warfarin (6 months) nor methylprednisolone have been effective in preventing restenosis although platelet inhibitors have been effective in preventing acute reocclusion after angioplasty. The calcium antagonists have also been unsuccessful in preventing restenosis, although they are still under study. Other agents currently under study include thromboxane inhibitors, prostacyclin mimetics, platelet membrane receptor blockers, thrombin inhibitors and angiotensin converting enzyme inhibitors. These agents must be given systemically, however, and attainment of a therapeutically effective dose may not be possible; antiproliferative (or anti-restenosis) concentrations may exceed the known toxic concentrations of these agents so that levels sufficient to produce smooth muscle inhibition may not be reached (Lang et al., 42 Ann. Rev. Med., 127–132 (1991); Popma et al., 84 Circulation, 1426–1436 (1991)).

Additional clinical trials in which the effectiveness for preventing restenosis of dietary fish oil supplements, thromboxane receptor antagonists, cholesterol lowering agents, and serotonin antagonists has been examined have shown either conflicting or negative results so that no pharmacological agents are as yet clinically available to prevent post-angioplasty restenosis (Franklin, S. M. and Faxon, D. P., 4 Coronary Artery Disease, 2-32-242 (1993); Serruys, P. W. et al., 88 Circulation, (part 1) 1588–1601, (1993).

Conversely, stents have proven useful in preventing reducing the proliferation of restenosis. Stents, such as the stent **10** seen in layout in FIG. **4**, balloon-expandable slotted metal tubes (usually but not limited to stainless steel), which when expanded within the lumen of an angioplastied coronary artery, provide structural support to the arterial wall. This support is helpful in maintaining an open path for blood flow. In two randomized clinical trials, stents were shown to increase angiographic success after PTCA, increase the stenosed blood vessel lumen and to reduce the lesion recurrence at 6 months (Serruys et al., 331 New Eng Jour. Med, 495, (1994); Fischman et al., 331 New Eng Jour. Med, 496–501 (1994). Additionally, in a preliminary trial, heparin coated stents appear to possess the same benefit of reduction in stenosis diameter at follow-up as was observed with non-heparin coated stents. Additionally, heparin coating appears to have the added benefit of producing a reduction

in sub-acute thrombosis after stent implantation (Serruys et al., 93 Circulation, 412–422, (1996). Thus, 1) sustained mechanical expansion of a stenosed coronary artery has been shown to provide some measure of restenosis prevention, and 2) coating of stents with heparin has demonstrated both the feasibility and the clinical usefulness of delivering drugs to local, injured tissue off the surface of the stent.

Numerous agents are being actively studied as antiproliferative agents for use in restenosis and have shown some activity in experimental animal models. These include: heparin and heparin fragments (Clowes and Karnovsky, 265 Nature, 25–626, (1977); Guyton, J. R. et al. 46 Circ. Res., 625–634, (1980); Clowes, A. W. and Clowes, M. M., 52 Lab. Invest., 611–616, (1985); Clowes, A. W. and Clowes, M. M., 58 Circ. Res., 839–845 (1986);. Majesky et al., 61 Circ Res., 296–300, (1987); Snow et al., 137 Am. J. Pathol., 313–330 (1990); Okada, T. et al., 25 Neurosurgery, 92–898, (1989) colchicine (Currier, J. W. et al., 80 Circulation, 11–66, (1989), taxol (ref), agiotensin converting enzyme (ACE) inhibitors (Powell, J. S. et al., 245 Science, 186–188 (1989), angiopeptin (Lundergan, C. F. et al., 17 Am. J. Cardiol. (Suppl. B); 132B-136B (1991), Cyclosporin A (Jonasson, L. et. al., 85 Proc. Nati, Acad. Sci., 2303 (1988), goat-anti-rabbit PDGF antibody (Ferns, G. A. A., et al., 253 Science, 1129–1132 (1991), terbinafine (Nemecek, G. M. et al., 248 J. Pharmacol. Exp. Thera., 1167–11747 (1989), trapidil (Liu, M. W. et al., 81 Circulation, 1089–1093 (1990), interferon-gamma (Hansson, G. K. and Holm, 84 J. Circulation, 1266–1272 (1991), steroids (Colburn, M. D. et al., 15 J. Vasc. Surg., 510–518 (1992), see also Berk, B. C. et al., 17 J. Am. Coll. Cardiol., 111B-117B (1991), ionizing radiation (ref), fusion toxins (ref) antisense oligonucleotides (ref), gene vectors (ref), and rapamycin (see below).

Of particular interest in rapamycin. Rapamycin is a macrolide antibiotic which blocks IL-2-mediated T-cell proliferation and possesses antiinflammatory activity. While the precise mechanism of rapamycin is still under active investigation, rapamycin has been shown to prevent the G.sub.1 to S phase progression of T-cells through the cell cycle by inhibiting specific cell cyclins and cyclin-dependent protein kinases (Siekierka, Immunol. Res. 13: 110–116, 1994). The antiproliferative action of rapamycin is not limited to T-cells; Marx et al. (Circ Res 76:412–417, 1995) have demonstrated that rapamycin prevents proliferation of both rat and human SMC in vitro while Poon et al. have shown the rat, porcine, and human SMC migratin can also be inhibited by rapamycin (J Clin Invest 98: 2277–2283, 1996). Thus, rapamycin is capable of inhibiting both the inflammatory response known to occur after arterial injury and stent implantation, as well as the SMC hyperproliferative response. In fact, the combined effects of rapamycin have been demonstrated to result in a diminished SMC hyperproliferative response in a rat femoral artery graft model and in both rat and porcine arterial balloon injury models (Gregory et al., Transplantation 55:1409–1418, 1993; Gallo et al., in press, (1997)). These observations clearly support the potential use of rapamycin in the clinical setting of post-angioplasty restenosis.

Although the ideal agent for restenosis has not yet been identified, some desired properties are clear: inhibition of local thrombosis without the risk systemic bleeding complications and continuous and prevention of the dequale of arterial injury, including local inflammation and sustained prevention smooth muscle proliferation at the site of angioplasty without serious systemic complications. Inasmuch as stents prevent at least a portion of the restenosis process, an agent which prevents inflammation and the proliferation of SMC combined with a stent may provide the most efficacious treatment for post-angioplasty restenosis.

Experiments

Agents: Rapamycin (sirolimus) structural analogs (macrocyclic lactones) and inhibitors of cell-cycle progression.

Delivery Methods: These can vary:

- Local delivery of such agents (rapamycin) from the struts of a stent, from a stent graft, grafts, stent cover or sheath.
- Involving comixture with polymers (both degradable and nondegrading) to hold the drug to the stent or graft.
- or entrapping the drug into the metal of the stent or graft body which has been modified to contain micropores or channels, as will be explained further herein.
- or including covalent binding of the drug to the stent via solution chemistry techniques (such as via the Carmeda process) or dry chemistry techniques (e.g. vapour deposition methods such as rf-plasma polymerization) and combinations thereof.
- Catheter delivery intravascularly from a tandem balloon or a porous balloon for intramural uptake.
- Extravascular delivery by the pericardial route.
- Extravascular delivery by the advential application of sustained release formulations.

Uses:

- for inhibition of cell proliferation to prevent neointimal proliferation and restenosis.
- prevention of tumor expansion from stents.
- preventingrowth of tissue into catheters and shunts inducing their failure.

1. Experimental Stent Delivery Method—Delivery from Polymer Matrix:

Solution of Rapamycin, prepared in a solvent miscible with polymer carrier solution, is mixed with solution of polymer at final concentration range 0.001 weight % to 30 weight % of drug. Polymers are biocompatible (i.e., not elicit any negative tissue reaction or promote mural thrombus formation) and degradable, such as lactone-based polyesters or copolyesters, e.g., polylactide, polycaprolactonglycolide, polyorthoesters, polyanhydrides; poly-amino acids; polysaccharides; polyphosphazenes; poly(ether-ester) copolymers, e.g., PEO-PLLA, or blends thereof. Nonabsorbable biocompatible polymers are also suitable candidates. Polymers such as polydimethylsiolxane; poly(ethylene-vingylacetate); acrylate based polymers or copolymers, e.g., poly(hydroxyethyl methylmethacrylate, polyvinyl pyrrolidinone; fluorinated polymers such as polytetrafluoroethylene; cellulose esters.

Polymer/drug mixture is applied to the surfaces of the stent by either dip-coating, or spray coating, or brush coating or dip/spin coating or combinations thereof, and the solvent allowed to evaporate to leave a film with entrapped rapamycin.

2. Experimental Stent Delivery Method—Delivery from Microporous Depots in Stent Through a Polymer Membrane Coating:

Stent, whose body has been modified to contain micropores or channels is dipped into a solution of Rapamycin, range 0.001 wt % to saturated, in organic solvent such as acetone or methylene chloride, for sufficient time to allow solution to permeate into the pores. (The dipping solution can also be compressed to improve the loading efficiency.) After solvent has been allowed to evaporate, the stent is dipped briefly in fresh solvent to remove excess surface bound drug. A solution of polymer, chosen from any identified in the first experimental method, is applied to the

stent as detailed above. This outer layer of polymer will act as diffusion-controller for release of drug.

3. Experimental Stent Delivery Method—Delivery Via Lysis of a Covalent Drug Tether:

Rapamycin is modified to contain a hydrolytically or enzymatically labile covalent bond for attaching to the surface of the stent which itself has been chemically derivatized to allow covalent immobilization. Covalent bonds such as ester, amides or anhydrides may be suitable for this.

4. Experimental Method—Pericardial Delivery:

A: Polymeric Sheet

Rapamycin is combined at concentration range previously highlighted, with a degradable polymer such as poly(caprolactone-gylcolid-e) or non-degradable polymer, e.g., polydimethylsiloxane, and mixture cast as a thin sheet, thickness range 10.mu. to 1000.mu. The resulting sheet can be wrapped perivascularly on the target vessel. Preference would be for the absorbable polymer.

B: Conformal Coating:

Rapamycin is combined with a polymer that has a melting temperature just above 37° C., range 40°-45° C. Mixture is applied in a molten state to the external side of the target vessel. Upon cooling to body temperature the mixture solidifies conformably to the vessel wall. Both non-degradable and absorbable biocompatible polymers are suitable.

As seen in the figures it is also possible to modify currently manufactured stents in order to adequately provide the drug dosages such as rapamycin. As seen in FIGS. **1***a*, **2***a* and **3***a*, any stent strut **10**, **20**, **30** can be modified to have a certain reservoir or channel **11**, **21**, **31**. Each of these reservoirs can be open or closed as desired. These reservoirs can hold the drug to be delivered. FIG. **4** shows a stent **40** with a reservoir **45** created at the apex of a flexible strut. Of course, this reservoir **45** is intended to be useful to deliver rapamycin or any other drug at a specific point of flexibility of the stent. Accordingly, this concept can be useful for "second generation" type stents.

In any of the foregoing devices, however, it is useful to have the drug dosage applied with enough specificity and enough concentration to provide an effective dosage in the lesion area. In this regard, the reservoir size in the stent struts must be kept at a size of about 0.0005" to about 0.003". Then, it should be possible to adequately apply the drug dosage at the desired location and in the desired amount.

These and other concepts will are disclosed herein. It would be apparent to the reader that modifications are possible to the stent or the drug dosage applied. In any event, however, the any obvious modifications should be perceived to fall within the scope of the invention which is to be realized from the attached claims and their equivalents.

What is claimed:

1. A device comprising a metallic stent, a biocompatible, nonabsorbable polymeric carrier, and a therapeutic agent, wherein:

said polymeric carrier comprises an acrylate-based polymer or copolymer, a fluorinated polymer, or a mixture thereof, and

said therapeutic agent is rapamycin, or a macrocyclic lactone analog thereof, and is present in an amount effective to inhibit neointimal proliferation.

2. The device according to claim **1** wherein said therapeutic agent is a macrocyclic lactone analog of rapamycin.

3. The device according to claim **1** that provides a controlled release of said therapeutic agent over a period of several weeks.

4. The device according to claim **2** that provides a controlled release of said therapeutic agent over a period of several weeks.

5. A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting a device according to any one of claims **1** to **4** in the lumen of said coronary artery.

* * * * *

Exhibit 6

Not Used

Exhibit 7

Office Action Summary	Application No.	Applicant(s)	
	11/467,035	WRIGHT ET AL.	
	Examiner	Art Unit	
	Suzette J. Gherbi	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 64-140 of copending Application No. 10/951,385. It is obvous to one having ordinary skill in the art that the current claims in this application 11/467,035 are met by the limitations of claims 64-140 (specifically 64, 82-83, 86, 88-89, 99 ect.) and are merely reworded in a varying manner. This is a provisional obviousness-type double patenting rejection.

Claims 1 and 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,585,764. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent 6,585,764 meets the claims specifically a copolymer polymer carrier and a therapeutic agent of rapamycin for the treatment of restenosis and the method claim is obvious because 17 states that stents is to combat restenosis and this is a well known occurrence of coronary angioplasty.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUZETTE GHERBI
PRIMARY EXAMINER
TECHNOLOGY CENTER 3700

17 November 2006

DOCKET NO.: CRDS-0067 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Carol Wright, et al.

Confirmation No.: **2954**

Application No.: **11/467,035**

Group Art Unit: **3738**

Filing Date: **August 24, 2006**

Examiner: **Suzettte J.J. Gherbi**

For: **Local Delivery Of Rapamycin For Treatment Of Proliferative Sequelae Associated With PTCA Procedures, Including Delivery Using A Modified Stent**

TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OF A PENDING APPLICATION

The owner, **Cordis Corporation**, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending Application Number **10/951,385**, filed September 28, 2004 and Application Number **11/466,983**, filed **August 24, 2006**. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on these applications are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of any patent granted on Application Number **10/951,385** and Application Number **11/466,983**, as shortened by any terminal disclaimer filed prior to the patent grant, in the event that any such granted patent:

expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR § 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

☒ The undersigned is an attorney of record.

Date: January 3, 2007

/S. Maurice Valla/
S. Maurice Valla
Registration No. 43,966

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

DOCKET NO.: CRDS-0067 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Carol Wright, et al.**	Confirmation No.: **2954**
Application No.: **11/467,035**	Group Art Unit: **3738**
Filing Date: **August 24, 2006**	Examiner: **Suzette J.J. Gherbi**

For: **Local Delivery Of Rapamycin For Treatment Of Proliferative Sequelae Associated With PTCA Procedures, Including Delivery Using A Modified Stent**

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

The owner, **Cordis Corporation**, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent Nos. **6,273,913, 6,585,764, and 6,808,536**. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the said prior patents are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the said prior patents, as presently shortened by any terminal disclaimer, in the event that any of said patents: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37

CFR § 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

☒ The undersigned is an attorney of record.

Date: January 3, 2007

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S. Maurice Valla
Registration No. 43,966

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Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
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Exhibit 8

Sandra Frantzen

From: ded_nefreply@ded.uscourts.gov
Sent: Monday, May 14, 2007 11:02 PM
To: ded_ecf@ded.uscourts.gov
Subject: Activity in Case 1:06-cv-00613-SLR Abbott Laboratories et al v. Johnson and Johnson Inc. et al Motion for Leave to File
Attachments: ENVELOPE.TXT

This is an automatic e-mail message generated by the CM/ECF system. Please DO NOT RESPOND to this e-mail because the mail box is unattended.
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U.S. District Court

District of Delaware

Notice of Electronic Filing

The following transaction was entered by Gaza, Anne on 5/15/2007 at 0:01 AM EDT and filed on 5/15/2007

Case Name: Abbott Laboratories et al v. Johnson and Johnson Inc. et al
Case Number: 1:06-cv-613
Filer: Abbott Laboratories
Advanced Cardiovascular Systems, Inc.
Document Number: 43

Docket Text:
MOTION for Leave to File *A Supplemental Complaint Or In The Alternative To Consolidate Related Actions* - filed by Abbott Laboratories, Advanced Cardiovascular Systems, Inc.. (Attachments: # (1) Exhibit A-B)(Gaza, Anne)

1:06-cv-613 Notice has been electronically mailed to:

Steven J. Balick sbalick@ashby-geddes.com, dfioravanti@ashby-geddes.com, jday@ashby-geddes.com, lmaguire@ashby-geddes.com, mkipp@ashby-geddes.com, nlopez@ashby-geddes.com, rgamory@ashby-geddes.com, tlydon@ashby-geddes.com

Christopher J. Buchko cbuchko@mhmlaw.com

Frederick L. Cottrell , III cottrell@rlf.com, garvey@rlf.com

John G. Day jday@ashby-geddes.com, dfioravanti@ashby-geddes.com, dharker@ashby-geddes.com, lmaguire@ashby-geddes.com, mkipp@ashby-geddes.com, nlopez@ashby-geddes.com, rgamory@ashby-geddes.com, sbalick@ashby-geddes.com, tlydon@ashby-geddes.com

Sandra A. Frantzen sfrantzen@mhmlaw.com

Anne Shea Gaza gaza@rlf.com, innis@rlf.com

Leland G. Hansen lhansen@mhmlaw.com

Lauren E. Maguire lmaguire@ashby-geddes.com

Edward A. Mas , II emas@mhmlaw.com

1:06-cv-613 Notice has been delivered by other means to:

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1079733196 [Date=5/15/2007] [FileNumber=387429-0]
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Document description: Exhibit A-B
Original filename:n/a
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Exhibit 9

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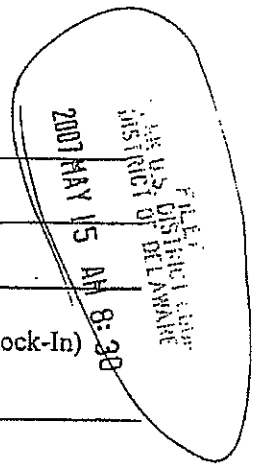

DATE: 5-15-07 TIME

CASE: Abbott

TITLE OF DOCUMENT(S): CS

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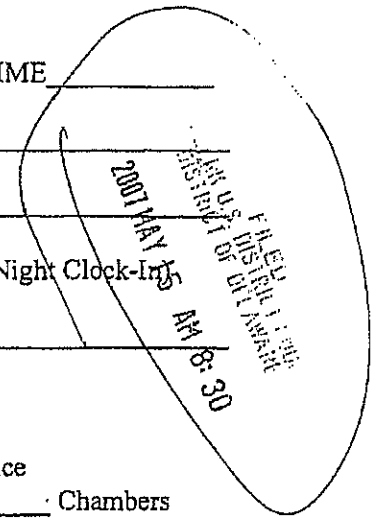

DATE: 5-15-07 TIME _____

CASE: Abbott

TITLE OF DOCUMENT(S): Summons JHJ

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DATE: 5-15-07 TIME _____

CASE: Abbott

TITLE OF DOCUMENT(S): Combined Disclosure

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DISTRICT OF DELAWARE

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DATE: 5-15-07 TIME _____

CASE: Abbott

TITLE OF DOCUMENT(S): Summons - Cordis

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( )	Del. Supreme Court	( )	Family Court
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DATE: 5-15-07 TIME_____

CASE: Abbott

TITLE OF DOCUMENT(S): Complaint

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( )	Del. Supreme Court	( )	Family Court
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(✓)	U.S. District Court	( )	Other _____

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SECRETARY/PARALEGAL: AFG ATTORNEY: FLC

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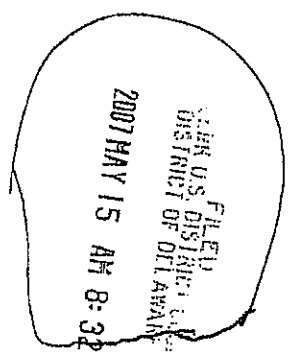

IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF DELAWARE

ABBOTT LABORATORIES and ABBOTT CARDIOVASCULAR SYSTEMS, INC.,	)	Civil Action No. 07-259
Plaintiffs,	)	
v.	)	JURY TRIAL DEMANDED
JOHNSON AND JOHNSON, INC. and CORDIS CORPORATION,	)	
Defendants.	)	

FILED
2007 MAY 15 AM 8:35
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE

COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT INVALIDITY AND NONINFRINGEMENT

Plaintiffs Abbott Laboratories and Abbott Cardiovascular Systems, Inc. (collectively "Abbott") bring this Complaint against Defendants Johnson and Johnson, Inc. and Cordis Corporation (collectively "J&J"). This is an action for declaratory judgment and injunctive relief that United States Patent No. 7,217,286 entitled "Load Delivery of Rapamycin for Treatment of Proliferative Sequelae Associated with PTCA Procedures, Including Delivery Using a Modified Stent" ("the Falotico '286 patent") is invalid and not infringed by Abbott. The Issue Notification for the Falotico '286 patent is attached as Exhibit A. The Falotico'286 patent is attached as Exhibit B. Abbott alleges as follows:

THE PARTIES

1. Abbott Laboratories is a corporation organized under the laws of the State of Illinois and has a principal place of business at 100 Abbott Park Road, North Chicago, Illinois.

2. Abbott Cardiovascular Systems, Inc. ("ACS"), formerly Advanced Cardiovascular Systems, Inc., is a corporation organized under the laws of the State of California

and has a principal place of business at 3200 Lakeside Drive, Santa Clara, California. ACS is a subsidiary of Abbott Laboratories.

3. On information and belief, Johnson and Johnson, Inc. is a corporation organized under the laws of the State of New Jersey and has a principal place of business at One Johnson and Johnson Plaza, New Brunswick, New Jersey.

4. On information and belief, Cordis Corporation ("Cordis") is a corporation organized under the laws of the State of Florida and has a principal place of business in Miami Lakes, Florida. Cordis is a subsidiary of Johnson and Johnson, Inc.

JURISDICTION AND VENUE

5. This action arises under the Patent Laws of the United States (35 U.S.C. § 1 *et seq.*).

6. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction, general and specific, over J&J.

8. On information and belief, J&J has systematic and continuous contacts in this judicial district.

9. On information and belief, J&J regularly avails itself of the benefits of this judicial district, including the jurisdiction of the courts.

10. On information and belief, J&J regularly transacts business within this judicial district.

11. On information and belief, J&J regularly sells products in this judicial district. J&J derives substantial revenues from sales in this district.

12. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c).

BACKGROUND

13. J&J, and in particular Cordis, directly competes with Abbott in the field of intravascular stents used to treat coronary artery disease.

14. The coronary stent industry is highly litigious. J&J, and in particular Cordis, has a well-known history of suing competitors in this field for patent infringement.

15. On three occasions within the last ten years, Cordis sued ACS in this district, alleging patent infringement involving angioplasty catheters or stents for treating coronary artery disease. (*Cordis Corporation, et al. v. Advanced Cardiovascular Systems, Inc, et al.*, C.A. No. 97-550-SLR; *Cordis Corporation, et al. v. Advanced Cardiovascular Systems, Inc., et al.*, C.A. No. 97-635-SLR; and *Cordis Corporation, et al. v. Advanced Cardiovascular Systems, Inc., et al.*, C.A. No. 98-065-SLR).

16. On three additional occasions within the last ten years, Cordis initiated patent infringement actions in this judicial district involving angioplasty catheters or stents for treating coronary artery disease. (*Cordis Corp. v. Boston Scientific Corp.*, C.A. No. 98-197-SLR; *Cordis Corp. v. Medtronic AVE, Inc.*, C.A. No. 00-886-SLR; and *Cordis Corp. v. Boston Scientific Corp.*, C.A. No. 03-027-SLR).

17. In early 2006, J&J and Boston Scientific Corporation ("BSC") each were bidding to acquire assets of Guidant Corporation ("Guidant"), which at the time was the parent corporation of ACS. In conjunction with BSC's bid, ACS would be acquired by Abbott Laboratories, which was the ultimate result.

18. One of the key assets of ACS was the XIENCE V drug eluting stent system ("XIENCE V"), which elutes a proprietary drug known as everolimus. ACS holds an exclusive

patent license to use everolimus for drug eluting stents. In clinical trials, everolimus has proven superior to other drugs.

19. On information and belief, J&J believed in early 2006 that the XIENCE V would be launched within a few months.

The Patent-in-Suit

20. United States Application No. 11/467,035 entitled "Load Delivery of Rapamycin for Treatment of Proliferative Sequelae Associated with PTCA Procedures, Including Delivery Using a Modified Stent" (the "Falotico '035 application") was filed on August 24, 2006.

21. The Falotico '035 application is related to and claims priority to United States Patent Nos. 6,808,536 ("the Wright '536 patent") and 6,585,764 ("the Wright '764 patent).

22. On information and belief, the subject matter claimed in the Falotico '035 application is not patentably distinct from subject matter claimed in at least the Wright '764 patent and the Wright '536 patent.

23. On information and belief, the Falotico '035 patent issued on May 15, 2007 as United States Patent No. 7,217,286.

J&J's Public Threats To Sue For Patent Infringement By XIENCE V

24. On information and belief, J&J undertook a public campaign to cast a cloud over the launch of the XIENCE V.

25. On information and belief, as a main thrust of this public campaign, J&J alleged that the XIENCE V would infringe patents allegedly owned by J&J and that J&J would sue Abbott for infringement by the XIENCE V following its launch. On information and belief, J&J's allegations related to at least the Wright '764 patent, the Wright '536 patent, and United States Patent No. 6,776,796 ("the Falotico '796 patent").

26. On information and belief, J&J broadcasted threatening statements to industry analysts regarding alleged infringement by the XIENCE V, for publication in furtherance of J&J's public campaign.

27. For example, the Prudential Equity Group, LLC published a report on January 20, 2006, titled "JNJ: Takes Off The Gloves In Its Fight With Boston Scientific For Guidant," attached as Exhibit G ("the Prudential report"). In the Prudential report, parties are identified by their stock symbols: ABT for Abbott, GDT for Guidant, JNJ for J&J, and BSX for BSC.

28. On information and belief, the Prudential report relied on information provided in pertinent part by J&J.

29. Among other things, the Prudential report stated:

> JNJ claims that 2 of its patents may be infringed if a company tries to launch a drug-eluting stent coated with a rapamycin derivative such as . . . GDT's everolimus. The potential for JNJ to prevent ABT and BSX from marketing the Xience-V DES, could give the GDT board pause for approving a BSX-GDT merger.
>
> * * *
>
> If BSX acquires GDT, BSX would sell GDT's vascular intervention (VI) business, including shared rights to GDT's promising everolimus-coated stent, Xience-V, to ABT. Although JNJ's patents have never been litigated, JNJ believes it has a strong intellectual property (IP) position with regard to the use of rapamycin derivatives on a stent. JNJ could pursue a preliminary injunction if ABT and BSX try to launch an everolimus-coated . . . stent. . . . According to JNJ, the key patents are the Falotico (6,776,796) and Wright (6,585,764) patents.

30. On information and belief, J&J anticipated and intended that Abbott and others would become aware of threatening statements made by J&J to Prudential analysts.

31. On January 23, 2006, A.G. Edwards & Sons, Inc. published a report titled "Healthcare Industry Note: The Game May Be Far From Over," attached as Exhibit D ("the AG Edwards report").

32. On information and belief, the AG Edwards report relied on information provided in pertinent part by J&J.

33. Among other things, the AG Edwards report stated:

> We have had conversations with Johnson & Johnson (JNJ) and Boston Scientific (BSX) and others recently that lead us to believe that the Guidant (GDT) game is far from over.
>
> * * *
>
> We were also reminded by JNJ that it had three patents related to '-limus' compounds that it thought precluded any other company from using such a compound on a stent. We were only given two patent numbers (6776796 [the Falotico '796 patent] and 6585764 [the Wright '764 patent]) . . . .

34. On information and belief, the third patent referenced in J&J's threatening statements was the Wright '536 patent.

35. On information and belief, J&J anticipated and intended that Abbott and others would become aware of threatening statements made by J&J to AG Edwards analysts.

36. On January 13, 2006, Citigroup published a report titled "An INTERESTing New Offer," attached as Exhibit E ("the January 13 Citigroup report").

37. On information and belief, the January 13, 2006 Citigroup report relied on information provided in pertinent part by J&J.

38. Among other things, the January 13, 2006 Citigroup report stated:

> The [Wright and Falotico] patents have never been challenged or enforced because no other company has launched a limus-based drug-eluting stent in the US, but are likely to eventually lead to litigation.

39. Citigroup published an additional report on March 23, 2006 titled "Deconstructing Xience," attached as Exhibit F ("the March 23, 2006 Citigroup report"). In the March 23, 2006 Citigroup report, J&J is identified by its stock symbol JNJ.

40. On information and belief, the March 23, 2006 Citigroup report relied on information provided in pertinent part by J&J.

41. Among other things, the March 23, 2006 Citigroup report stated:

> Everolimus will likely face two IP challenges from JNJ as both its Falotico and Wright patents claim the use of a limus analogue on a stent.

42. On information and belief, J&J anticipated and intended that Abbott and others would become aware of threatening statements made by J&J to Citigroup analysts.

43. On January 30, 2006, Lehman Brothers published a report titled "The Risks – Part I," attached as Exhibit G ("the Lehman Brothers report"). In the Lehman Brothers report, parties are identified by their stock symbols: ABT for Abbott; GDT for Guidant; and JNJ for J&J.

44. On information and belief, the Lehman Brothers report relied on information provided in pertinent part by J&J.

45. Among other things, the Lehman Brothers report stated:

There are even hypothetical litigations to contend with as JNJ has strongly suggested that they feel GDT and ABT may violate JN/Wyeth DES patents covering the "limus" family of drugs.

46. On information and belief, J&J anticipated and intended that Abbott and others would become aware of threatening statements made by J&J to Lehman Brothers analysts.

47. On March 14, 2006, Merril Lynch published a report titled "More legal wrangling for J&J possible," attached as Exhibit H ("the Merril Lynch report"). In the Merril Lynch report, J&J is identified by its stock symbol JNJ.

48. On information and belief, the Merril Lynch report relied on information provided in pertinent part by J&J.

49. Among other things, the Merril Lynch report stated:

> JNJ has two patents (Wright and Falotico) which appear to relate to the elution of characteristics of "olimus" compounds; JNJ's Cypher DES uses sirolimus, a member of the olimus family of drugs; other olimus drugs include Guidant's everolimus and Abbott/Medtronic's zotarolimus (ABT-578). The European launch of Guidant's Xience DES, which the company has targeted for Q2:06, could trigger possible legal activity since we understand U.S. patent law prohibits domestic manufacture of a product for sale outside the U.S. if there's been infringement of intellectual property.

50. On information and belief, J&J anticipated and intended that Abbott and others would become aware of threatening statements made by J&J to Merril Lynch analysts.

51. On information and belief, J&J broadcast threatening statements to other news outlets regarding alleged infringement by the XIENCE V, for publication in furtherance of J&J's public campaign.

52. On January 23, 2006, the International Herald Tribune published an article headlined "J&J works to discredit rival offer for Guidant," attached as Exhibit I ("the International Herald article").

53. On information and belief, the International Herald article relied on information provided in pertinent part by J&J.

54. Among other things, the International Herald article stated:

> "J&J is communicating to the Street that Boston Scientific's $80-a-share offer for Guidant is fraught with uncertainty," Lawrence Biegelsen, an analyst with Prudential in New York, said in a note to clients sent on Friday.
>
> * * *
>
> Johnson & Johnson's campaign consists of telling analysts and shareholders that Boston Scientific is in over its head and is tempting patent litigation that may undercut Boston Scientific's plans.
>
> "They're trying to tell all of us that there are patents out there that they have that they feel can stop Boston Scientific," said Jan David Wald, an analyst with A.G. Edwards. Wald said he had been called by a Johnson & Johnson employee, whom he declined to name.
>
> Johnson & Johnson told analysts it was considering filing patent infringement lawsuits over stent drug coatings to keep Boston Scientific and its bidding partner, Abbott Laboratories, from profiting from the new Guidant devices, according to Biegelsen of Prudential.
>
> * * *

> Boston Scientific and J&J have been fighting in court for years over patent-infringement cases related to stent design. At the moment, the two companies are alone in the U.S. stent market, with Boston Scientific holding a 55 percent share.
>
> * * *
>
> The potential for Johnson & Johnson to prevent Abbott and Boston Scientific from marketing Guidant's next-generation heart stent "could give the Guidant board pause for approving a Boston Scientific-Guidant merger," Biegelsen said. "J&J claims that two of its patents may be infringed if a company tries to launch a drug-eluting stent coated with" . . . Guidant's everolimus, he wrote.

55. On January 20, 2006, the Boston Globe published an article headlined "Suitors take Guidant fight to The Street," attached as Exhibit J ("the Boston Globe article").

56. On information and belief, the Boston Globe article relied on information provided in pertinent part by J&J.

57. Among other things, the Boston Globe article stated:

> [J&J] has also raised prospects that it could use patents and existing ties to Guidant to derail or complicate Boston Scientific's offer, said Matthew Dodds, an analyst for Citigroup who is skeptical about Guidant's value to both companies.

58. Also on January 20, 2006, Crain's Chicago Business published an article headlined "Abbott stock falls on concerns over success of Guidant bid," attached as Exhibit K ("the Crain's article").

59. On information and belief, the Crain's article relied on information provided in pertinent part by J&J.

60. Among other things, the Crain's article stated:

The analyst, Prudential Equity Group, LLC's Larry Biegelsen, reported that Guidant's board could balk at Boston Scientific and Abbott's joint bid because Johnson & Johnson, a competing bidder for Guidant, claims its patents would be violated if Abbott markets its own drug-eluting stent or those made by Guidant.

61. On January 21, 2006, Reuters published an article headlined "Abbott, Boston shares off J&J patent threat," attached as Exhibit L ("the Reuters article").

62. On information and belief, the Reuters article relied on information provided in pertinent part by J&J.

63. Among other things, the Reuters article stated:

One analyst, who asked not to be named, said J&J management was making rounds on Wall Street trying to fan fears about the Boston Scientific bid. The analyst said J&J was arguing that Boston Scientific's bid was breaking its bank, that its assumptions on Guidant's cardiac rhythm management were too aggressive and that there was intellectual property infringement that would limit potential of important products.

64. On January 24, 2006, Medical Device Daily published an article headlined "J&J offer rumors persist as Guidant has more ICD issues," attached as Exhibit M ("the Medical Device Daily article").

65. On information and belief, the Medical Device Daily article relied on information provided in pertinent part by J&J.

66. Among other things, the Medical Device Daily article stated:

Fueling this speculation were rumors, some of which apparently were planted by J&J personnel as part of an organized campaign to undermine the Boston Scientific offer in

the minds of analysts, that two of its patents may be infringed if an unnamed company tries to launch a drug-eluting stent coated withed a derivative of rapamycin.

67. On January 26, 2006, The Wall Street Journal published an article headline "Boston Scientific Faces Pivotal Test After Victory in Fight for Guidant," attached as Exhibit N ("the Wall Street Journal article").

68. On information and belief, the Wall Street Journal article relied on information provided in pertinent part by J&J.

69. Among other things, the Wall Street Journal article stated that:

> Another potential wrinkle arises in the intellectual-property rights surrounding stents –an area that's been the subject of extensive litigation in the industry. Citigroup analyst Matthew Dodds says J&J holds patents on methods of using "limus-type drugs on stents - - including the everolimus on Guidant's stent, as well as a drug on an Abbott stent.

70. On information and belief, J&J anticipated and intended that Abbott and others would become aware of threatening statements made by J&J to analysts and others.

71. On information and belief, J&J made additional threatening statements to industry analysts, asserting that J&J could prevent Abbott from making or selling the XIENCE V by suing for infringement of patents in the Wright and/or Falotico families. On information and belief, J&J anticipated and intended that Abbott and others would become aware of these threatening statements.

72. Abbott and others did become aware of J&J's threatening statements.

73. For example, on January 20, 2006, Avram Goldstein of Bloomberg contacted Abbott regarding the Wright and Falotico patents in relation to the XIENCE V.

74. On January 13, 2006, Bruce Nudell of Sanford C. Bernstein contacted Guidant regarding the Wright and Falotico patents in relation to the XIENCE V.

75. Also on January 13, 2006, The Shaw Group contacted Guidant regarding the Wright and Falotico patents in relation to the XIENCE V.

76. On January 20, 2006, Avram Goldstein of Bloomberg contacted Guidant regarding the Wright and Falotico patents in relation to the XIENCE V.

77. Again on January 20, 2006, Barnaby Feder of the New York Times contacted Guidant regarding the Wright and Falotico patents in relation to the XIENCE V.

78. On January 31, 2006, Steve Silva of Joele Frank contacted Guidant regarding the Wright and Falotico patents in relation to the XIENCE V.

79. On March 23, 2006, Jennifer B. Pearlman of Burgundy Asset Management contacted Guidant regarding the Wright and Falotico patents in relation to the XIENCE V.

80. On information and belief, J&J intended to create a substantial controversy between J&J and Abbott regarding alleged infringement of patents in the Wright and/or Falotico families by the XIENCE V.

81. On information and belief, J&J intended to create the apprehension in Abbott and others that J&J would sue Abbott, asserting that the XIENCE V allegedly infringes patents in the Wright and/or Falotico families.

82. In March 2006, Guidant publicly announced that the XIENCE V launch would be delayed due to an issue related to manufacturing.

83. The XIENCE V was subsequently launched in Europe. On information and belief, J&J is aware that the XIENCE V has launched and is preparing to sue Abbott for infringement by the XIENCE V of patents in the Wright and/or Falotico families.

84. On information and belief, J&J has never withdrawn or retracted any of its threatening statements that, following the launch of the XIENCE V, J&J would sue Abbott for infringement of the patents in the Wright and/or Falotico families.

85. On information and belief, in furtherance of its campaign to cast a cloud over the launch of the XIENCE V, J&J made threatening statements to Guidant.

86. On January 12, 2006, J&J contacted Guidant and informed Guidant that if Boston Scientific acquired Guidant, Abbott and Boston Scientific would have problems with the Wright and Falotico patent families.

87. On January 13, 2006, J&J again contacted Guidant. J&J sent Guidant a document asserting that J&J's intellectual property portfolio included patents directed to Everolimus when used on a stent, Abbott would not receive access to these patent in the event that Boston Scientific were to acquire Guidant, and any drug eluting stent using Everolimus, including the XIENCE V, may infringe these patents.

88. On information and belief, by these statements J&J intended to create a substantial controversy between J&J and Abbott regarding alleged infringement of patents in the Wright and/or Falotico families by the XIENCE V.

89. On information and belief, by these statements J&J intended to create the apprehension in Abbott and others that J&J would sue Abbott, following the launch of the XIENCE V, asserting that the XIENCE V allegedly infringes patents in the Wright and/or Falotico families.

J&J's Assertions In The Patent Office Of Infringement By XIENCE V

90. On August 24, 2006, J&J filed a "Petition to Make Special Because of Actual Infringement ("the Petition") with the United States Patent and Trademark Office in the matter of

United States Application Serial No. 11/467,035 ("the Falotico '035 application"). On information and belief, on May 15, 2007, the Falotico '035 application issued as United States Patent No. 7,217,286. A copy of the Petition is attached as Exhibit O.

91. In the Petition, J&J asserted that it could sue Abbott for infringement by the XIENCE V immediately upon issuance of the Falotico '035 application as a patent. Among other things, counsel for J&J asserted:

> Guidant's vascular business has recently been acquired by Abbott Laboratories (Exhibit 3). Abbott has announced that it intends to launch the XIENCE™ V in Europe in the third quarter of 2006 (Exhibit 4).
>
> * * *
>
> I have made a rigid comparison of the XIENCE™ V product, as described in Guidant press releases, with the claims of the instant application. In my opinion, the XIENCE™ V product is unquestionably within the scope of at least claims 1 to 5 on file in this application.
>
> * * *
>
> It is therefore my opinion that Guidant is making a product in the United States to support the European launch that is unquestionably within the scope of at least claims 1 to 5 of the instant application, and that a patent containing these claims could immediately be asserted upon issue.

92. On information and belief, J&J intended to create a substantial controversy between J&J and Abbott regarding the XIENCE V's alleged infringement of the Falotico '286 patent.

93. On information and belief, J&J intended to create the apprehension in Abbot and others that J&J would sue Abbott asserting that the XIENCE V allegedly infringes the Falotico '286 patent.

94. On information and belief, J&J is preparing to sue Abbott for infringement by the XIENCE V of the Falotico '286 patent.

J&J Has Recently Sued Abbott In An Attempt To Interfere With The XIENCE V Launch

95. On September 25, 2006, J&J filed a complaint in the District Court for the Southern District of New York. Among other things, J&J alleges that Abbott Laboratories tortiously interfered with J&J's intended acquisition of Guidant. The complaint seeks no less than $5.5 billion in damages. A copy of the complaint is attached as Exhibit P.

96. Although the events cited in the complaint occurred over eight months ago, J&J timed the lawsuit, on information and belief, in anticipation of the then imminent launch of the XIENCE V. Both the timing of the lawsuit and the amount of the damages claimed manifest J&J's intent to cast a cloud over Abbott and interfere with the then imminent launch of the XIENCE V.

The XIENCE V Launch

97. Abbott has manufactured and continues to manufacture, at its facilities in the United States, thousands of the XIENCE V.

98. On information and belief, J&J created a substantial controversy between J&J and Abbott regarding the alleged infringement of the Falotico '286 patent by the XIENCE V.

99. Abbott has a reasonable apprehension that J&J intends to sue Abbott for infringement of the Falotico '286 patent by the XIENCE V.

CLAIM I

INVALIDITY AND NONINFRINGEMENT OF U.S. PATENT NO.7,217,286

100. Abbott realleges and incorporates by reference the allegations set forth in paragraphs 1-99.

101. J&J's actions have created a substantial controversy between J&J and Abbott regarding alleged infringement of the Falotico '286 patent by the XIENCE V.

102. J&J has asserted rights under the Falotico '286 patent against the XIENCE V.

103. J&J's actions have placed Abbott in reasonable apprehension that it will be sued for alleged infringement of the Falotico '286 patent by the XIENCE V.

104. On information and belief, the claims of the Falotico '286 patent are invalid for failure to meet the requirements for patentability, including the requirements of 35 U.S.C. §§ 102, 103, and 112.

105. The XIENCE V does not infringe any valid claim of the Falotico '286 patent.

106. An actual and justiciable controversy exists between Abbott and J&J regarding invalidity and noninfringement of the Falotico '286 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request entry of judgment in their favor that:

(a) each and every claim of U.S. Patent No. 7,217,286 is invalid;

(b) Plaintiffs are not liable for any infringement, for any contributory infringement, or for inducing the infringement of U.S. Patent No. 7,217,286;

(c) Defendants and their officers, agents, employees, representatives, counsel and all persons in active concert or participation with any of them, directly or indirectly, be enjoined from threatening or charging infringement of, or instituting any action for infringement of U.S.

Patent No. 7,217,286 against Plaintiffs, their suppliers, customers, distributors or users of their products;

(d) Defendants pay to Plaintiffs the costs and reasonable attorneys fees incurred by Plaintiffs in this action; and

(e) Plaintiffs be granted such other and further relief as this Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all issues so triable.

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ATTORNEYS FOR PLAINTIFFS ABBOTT LABORATORIES and ABBOTT CARDIOVASCULAR SYSTEMS, INC.

Date: May 15, 2007

Exhibit 10

MIME-Version:1.0
From:njdefiling@njd.uscourts.gov
To:ecfhelp@localhost.localdomain
Bcc:drobinson@robinsonlivelli.com, graffield@robinsonlivelli.com,
njdnef_Bongiovanni@njd.uscourts.gov, njdnef_pisano@njd.uscourts.gov
Message-Id:<1980864@njd.uscourts.gov>
Subject:Activity in Case 3:07-cv-02265-JAP-TJB CORDIS CORPORATION v. ABBOTT LABORATORIES Complaint
Content-Type: text/html

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U.S. District Court

District of New Jersey [LIVE]

Notice of Electronic Filing

The following transaction was entered on 5/15/2007 at 11:07 AM EDT and filed on 5/15/2007

Case Name: ~~CORDIS CORPORATION v. ABBOTT LABORATORIES~~
Case Number: 3:07-cv-2265
Filer: CORDIS CORPORATION
Document Number: 1

Docket Text:
COMPLAINT against ABBOTT LABORATORIES (Filing fee $ 350 receipt number 1479428.) Jury Demand, filed by CORDIS CORPORATION. (Attachments: # (1) Certification pursuant to local civil rule 201.1# (2) Disclosure Statement)(ck)

3:07-cv-2265 Notice has been electronically mailed to:

DONALD A. ROBINSON drobinson@robinsonlivelli.com, graffield@robinsonlivelli.com

3:07-cv-2265 Notice has been delivered by other means to:

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1046708974 [Date=5/15/2007] [FileNumber=1980862-0
] [8f90e9df2c2bb47ced08d531dfa048094fd6d3dafacec4d9a784c5c757c150e2c38
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Document description: Certification pursuant to local civil rule 201.1
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1046708974 [Date=5/15/2007] [FileNumber=1980862-1
] [9bd89363feced55aa18cc744b14c7e64ded176872fe981d2be37d84d34d27e04435

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Attorneys for Plaintiff
Cordis Corporation

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CORDIS CORPORATION Plaintiff, vs. ABBOTT LABORATORIES., Defendant.	Civil Action No. **COMPLAINT AND DEMAND FOR JURY TRIAL** ***Document Filed Electronically***

Plaintiff Cordis Corporation, by its attorneys, alleges as follows:

THE PARTIES

1. Plaintiff Cordis Corporation ("Cordis"), 33 Technology Drive, Warren, New Jersey, is a Florida corporation with a principal place of business in Warren, New Jersey. Cordis also has facilities in Clark, New Jersey. Cordis is a pioneer in developing invasive

treatments for vascular disease, including the CYPHER® drug-eluting stent, a drug/device combination for the treatment of coronary artery disease.

2. Upon information and belief, Defendant Abbott Laboratories ("Abbott"), 100 Abbott Park Road, North Chicago, IL 60064, is an Illinois corporation with a principal place of business in Illinois.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over Cordis's patent infringement claims under 28 U.S.C. § 1331 and 1338(a).

4. This Court has personal jurisdiction over Abbott. On information and belief, Abbott has systematic and continuous contacts in this judicial District, regularly transacts business within this judicial District, and regularly avails itself of the benefits of this judicial District. For example, Abbott is registered to do business in New Jersey, and has facilities located in this District, including in East Windsor, Cranbury, South Brunswick, Edison, Whippany, and Parsippany, New Jersey. On information and belief, Abbott also has numerous employees in this District, derives substantial revenues from its business operations and sales in this district, and pays taxes in New Jersey based on revenue generated in this District. On information and belief, Abbott also sells and distributes medical devices in this District, including vascular devices.

5. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

FACTUAL ALLEGATIONS

6. Abbott is the manufacturer of a drug-eluting stent named XIENCE V Everolimus Eluting Coronary Stent System ("XIENCE V stent"). Abbott has manufactured

thousands of XIENCE V products in the United States for sale in Europe and Asia. Abbott launched the XIENCE V stent in Europe and the Asia Pacific regions in 2006.

7. On May 15, 2007, the United States Patent and Trademark Office ("USPTO") duly and legally issued United States Patent No. 7,217,286, entitled "Local Delivery of Rapamycin For Treatment of Proliferative Sequelae Associated With PTCA Procedures, Including Delivery Using a Modified Stent" (the "'286 patent"). The '286 patent issued to Robert Falotico and Gerard H. Llanos, and is assigned to Cordis. Cordis holds all right, title and interest in and to the '286 patent.

8. Abbott has been and is performing acts covered by the claims of the '286 patent, including making and/or using the XIENCE V stent in the United States for sale in Europe and Asia.

9. At present, there are only two companies marketing in the United States drug eluting stents – Cordis and Boston Scientific Corporation. Abbott has publicly announced that it plans to seek approval from the United States Food and Drug Administration in the second quarter of 2007 to sell the XIENCE V stent in the United States. Abbott has also publicly announced that, assuming it receives regulatory approval, it plans to launch the XIENCE V stent in the United States in the first half of 2008. Upon its launch in the United States, the XIENCE V stent will compete directly with Cordis's CYPHER stent, reducing Cordis's market share and causing irreparable harm to Cordis.

COUNT I: INFRINGEMENT OF THE '286 PATENT

10. Cordis realleges paragraphs 1-9 above as if fully set forth herein.

11. Abbott is infringing the '286 patent in violation of 35 U.S.C. § 271, including by making and/or using the XIENCE V stent in the United States.

12. Abbott had and has actual notice of the '286 patent, and is infringing the '286 patent with knowledge of Cordis's patent rights. Abbott's actions are willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, Cordis prays for the following relief against Abbott:

1. For judgment in favor of Cordis that Abbott is infringing Cordis's patent;

2. For a preliminary and permanent injunction pursuant to 35 U.S.C. § 283 prohibiting Abbott from making, using, selling, or offering for sale the infringing products in the United States;

3. For an award of damages for Abbott's infringement of Cordis's patent, together with interest (both pre-and post-judgment), costs, and disbursements as fixed by this Court under 35 U.S.C. § 284;

4. For a determination that Abbott's infringement is willful, and an award of treble the amount of damages and losses sustained by Cordis as a result of Abbott's infringement, under 35 U.S.C. § 284;

5. For a determination that this is an exceptional case within the meaning of 35 U.S.C. § 285, and an award to Cordis of its reasonable attorneys' fees; and

6. For such other and further relief in law or in equity to which Cordis may be justly entitled.

DEMAND FOR JURY TRIAL

Cordis demands a trial by jury of any and all issues triable of right before a jury.

Dated: May 15, 2007.

By:

s/Donald A. Robinson

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ATTORNEYS FOR PLAINTIFF CORDIS CORPORATION

Exhibit 11

Docket No.: CRDS-0067/JJI-51-CON4 **PATENT**
Application No: 11/467,035

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Wright, et al.**	Confirmation No.: **2954**
Application No.: **11/467,035**	Group Art Unit: **3738**
Filing Date: **August 24, 2006**	Examiner: **Suzettte Gherbi**

For: **Local Delivery Of Rapamycin For Treatment Of Proliferative Sequelae Associated With PTCA Procedures, Including Delivery Using A Modified Stent**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT, REQUEST AND PROCESSING FEE TO DELETE AND/OR ADD TO ORIGINAL ERRONEOUSLY NAMED OR NOT NAMED INVENTOR(S) IN DECLARATION - NONPROVISIONAL APPLICATION PURSUANT TO 37 CFR § 1.48(a)

This amendment and request is to correct the incorrect original naming of inventor(s) in the declaration under 37 CFR § 1.48(a).

Addition and Deletion of Inventor(s)

☒ Add the following previously unnamed person as inventor of this application:

Robert Falotico

☒ Delete the following previously named persons as inventors of this application:

Carol Wright

Ronald Rakos

Kristen King

Attachments

Attached is

- ☒ A statement from each person being added as an inventor that the error in inventorship occurred without deceptive intention on his or her part. 37 CFR § 1.48(a)(2).
- ☒ A statement from each person being deleted as an inventor that the error in inventorship occurred without deceptive intention on his or her part. 37 CFR § 1.48(a)(2). (1) Carol Wright; (2) Ronald Rakos and (3) Kristin King.
- ☒ a declaration by each of the actual inventor(s) as required by 37 CFR § 1.63 (or as permitted by §§§ 1.42, 1.43, or 1.47. 37 CFR § 1.48(a)(3)). (1) Robert Falotico and (2) Gerard H. Llanos.
- ☒ written consent of the assignee. 37 CFR § 1.48(a)(5).
- ☒ Supplemental Application Data Sheet

Processing Fee Payment (37 CFR § 1.17(i))

- ☒ Please charge Deposit Account No. 23-3050 in the amount of **$130.00**.
- ☒ The Commissioner is hereby authorized to charge any deficiency or credit any overpayment of the fees associated with this communication to Deposit Account No. 23-3050.

Date: 1/9/07

S. Maurice Valla
Registration No. 43,966

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

Exhibit 12

From: Leland Hansen
Sent: Wednesday, May 16, 2007 2:17 PM
To: 'rcass@Sidley.com'
Cc: 'dpritikin@sidley.com'; 'pveith@Sidley.com'
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Russ:

Any word on the stipulation?

For the complaint filed in New Jersey, I assume that you received a Notice of Electronic Filing via email when the filing was complete. Please forward the email to me. If you received a Notice is some other fashion, please send as a pdf file. If this is a problem for some reason, please explain.

Thanks.

Leland

From: Leland Hansen
Sent: Wednesday, May 16, 2007 9:37 AM
To: 'rcass@Sidley.com'
Cc: 'dpritikin@sidley.com'; 'pveith@Sidley.com'
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Russ:

I have attached a stipulation for your review.

Also, per my earlier request, please email a copy of all papers associated with the NJ complaint as filed, including the Notice of Electronic Filing.

I will appreciate your prompt attention to these matters.

Leland

From: Leland Hansen
Sent: Tuesday, May 15, 2007 5:46 PM
To: 'rcass@Sidley.com'
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Russ:

I have attached the motion and related papers.

With respect to the complaint that you filed in NJ, please send us a copy of the complaint as filed (including any exhibits) and all related documents (including the Notice of Electronic Filing).

Thank you for agreeing to a 1 week extension for our opposition to the motion to dismiss. We will prepare a stipulation as we discussed.

Leland

From: rcass@Sidley.com [mailto:rcass@Sidley.com]
Sent: Tuesday, May 15, 2007 4:50 PM
To: Leland Hansen
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Could you send me copies? Thanks.

From: LHANSEN@mcandrews-ip.com [mailto:LHANSEN@mcandrews-ip.com]
Sent: Tuesday, May 15, 2007 12:29 PM
To: Cass, Russell E.
Cc: Pritikin, David T.; Veith, Paul E.
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Russ:

Do you still need copies of the motion and related documents?

Leland

From: Leland Hansen
Sent: Tuesday, May 15, 2007 10:56 AM
To: 'rcass@Sidley.com'
Cc: dpritikin@sidley.com; pveith@Sidley.com
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

The motion and related documents should be available via pacer. I will send courtesy copies when I have them.

From: rcass@Sidley.com [mailto:rcass@Sidley.com]
Sent: Tuesday, May 15, 2007 10:44 AM
To: Leland Hansen
Cc: dpritikin@sidley.com; pveith@Sidley.com
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Leland:

I don't believe I received a copy of the Motion for Leave to File a Supplemental Complaint or in the Alternative to Consolidate Related Actions. Could you send me a copy?

Russ

From: LHANSEN@mcandrews-ip.com [mailto:LHANSEN@mcandrews-ip.com]
Sent: Tuesday, May 15, 2007 10:19 AM
To: Cass, Russell E.
Cc: Pritikin, David T.; Veith, Paul E.
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Russ:

Because J&J would not stipulate, we have filed a Complaint For Declaratory Judgment Of Patent Invalidity And Noninfringement for U.S. Patent No. 7,217,286 (the Falotico 286 patent). I have attached courtesy copies of the complaint and related documents.

Also, we filed a Motion For Leave To File A Supplemental Complaint Or In The Alternative To Consolidate Related Actions. The motion and related documents were served previously.

If J&J or Cordis has filed or files a complaint for the Falotico 286 patent, the Wright 764 patent, the Wright 536 patent, the Falotico 796 patent, or any related patent, please promptly provide us with courtesy copies.

Leland

From: rcass@Sidley.com [mailto:rcass@Sidley.com]
Sent: Monday, May 14, 2007 6:07 PM
To: Leland Hansen
Cc: dpritikin@sidley.com; pveith@Sidley.com
Subject: RE: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Leland:

Paul is out of town, so I am responding to your e-mail. We have contacted our client, and J&J does not consent to supplementing the complaint to add a new declaratory judgment claim or consolidating the present action with a new declaratory judgment complaint. J&J also will not be withdrawing its motion to dismiss.

Russ

From: LHANSEN@mcandrews-ip.com [mailto:LHANSEN@mcandrews-ip.com]
Sent: Monday, May 14, 2007 4:48 PM
To: Veith, Paul E.
Cc: Pritikin, David T.; Cass, Russell E.
Subject: Abbott Labs v. J&J, C.A. No. 06-613 SLR

Paul:

I am writing to follow up on my prior voicemail. I have tried to call you several times but each time I have been immediately directed to your voicemail.

We are aware that U.S. Patent No. 7,217,286 will issue tomorrow (May 15) from application no. 11/467,035 and U.S. Patent No. 7,223,286 will issue on May 29 from application no. 10/951,385. Please let us know today whether J&J will stipulate that Abbott may either (1) supplement the complaint to add a declaratory judgment claim for each of the new patents or (2) consolidate the present action with new declaratory judgment complaints for each of the new patents.

Also, please let us know today whether J&J will withdraw its motion to dismiss.

Leland

Leland G. Hansen
McANDREWS, HELD & MALLOY, LTD.
500 WEST MADISON STREET, 34th FLOOR
CHICAGO, ILLINOIS 60661
312 775 8000 (T)
312 775 8013 (D)
312 775 8100 (F)
lhansen@mcandrews-ip.com
www.mcandrews-ip.com

http://www.mcandrews-ip.com

Exhibit 13

LOCAL CIVIL AND CRIMINAL RULES

OF THE

UNITED STATES DISTRICT COURT

FOR THE

DISTRICT OF NEW JERSEY

With Revisions as of March 9, 2007

TABLE OF CONTENTS

LOCAL CRIMINAL RULES

CONVERSION TABLES

COURT'S APPENDICES

(c) Except in an emergency, no papers shall be left with or mailed to a Judge for filing, but all pleadings shall be filed with the Clerk of the Court.

(d) When papers are filed, the Clerk shall endorse thereon the date and time of filing.

(e) Parties shall furnish to the Clerk forthwith, upon demand, all necessary copies of any pleading, judgment or order, or other matter of record in a cause, so as to permit the Clerk to comply with the provisions of any statute or rule. Plaintiff or plaintiff's attorney upon filing a complaint, and defendant or defendant's attorney upon filing a notice of removal pursuant to 28 U.S.C. §1446, shall furnish to the Clerk a completed civil cover sheet and four (4) copies of such pleading in addition to any copies required to be filed under the Federal Rules of Civil Procedure. All such copies of the notice of removal shall also include a copy of all papers required to be filed under 28 U.S.C. §1446(a). Upon receipt, the Clerk shall transmit one copy to the Judges to whom the case is assigned.

(f) Any papers received by the Clerk without payment of such fees as may be fixed by statute or by the Judicial Conference of the United States for the filing thereof shall be marked "received" and the date and time of receipt shall be noted thereon.

Amended: March 14, 2001

Source: L.Civ.R. 5.1(a) - G.R. 9.A.; L.Civ.R. 5.1(b) - G.R. 9.B.; L.Civ.R. 5.1(c) - G.R. 8.D.; L.Civ.R. 5.1(d) - G.R. 8.C.; L.Civ.R. 5.1(e) - G.R. 8.E., G.R. 10.A.

Civ. RULE 5.2 ELECTRONIC SERVICE AND FILING DOCUMENTS

Papers served and filed by electronic means in accordance with procedures promulgated by the Court are, for purposes of Federal Rule of Civil Procedure 5, served and filed in compliance with the local civil and criminal rules of the District of New Jersey

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
ELECTRONIC CASE FILING POLICIES AND PROCEDURES

1. Definitions.

(a) "Electronic Filing System" refers to the court's automated system that receives and stores documents filed in electronic form. The program is part of the CM/ECF (Case Management/Electronic Case Filing) software which was developed for the Federal Judiciary by the Administrative Office of theUnited States Courts.

(b) "Filing User" is an attorney who has a court-issued login and password to filedocuments electronically.

(c) "Notice of Electronic Filing" is a notice automatically generated by the Electronic Filing System at the time a document is filed with the system, setting forth the time of filing, the name of the party and attorney filing the document, the type of document, the text of the docket entry,

the name of the party and/or attorney receiving the notice, and an electronic link (hyperlink) to the filed document, which allows recipients to retrieve the document automatically.

(d) "PACER" (Public Access to Court Electronic Records) is an automated system that allows an individual to view, print, and download court docket information over the internet.

(e) "PDF" refers to Portable Document Format. A document created with a word processor, or a paper document which has been scanned, must be converted to portable document format to be filed electronically with the court. Converted files contain the extension ".pdf."

(f) "Proposed Order" is a draft document submitted by an attorney for a judge's signature. A proposed order shall accompany a motion or other request for relief as an electronic attachment to the document.

(g) "Document" shall include pleadings, motions, briefs, memoranda, exhibits, certifications, declarations, affidavits, papers, orders, notices, and any other filing by or to the court.

(h) "Technical Failure" is defined as a malfunction of court owned/leased hardware, software, and/or telecommunications facility which results in the inability of a Filing User to submit a filing electronically. Technical failure does not include malfunctioning of a Filing User's equipment.

(i) "Paper Filing" is submitting a document in hard copy on paper.

(j) "Pay.gov" is an electronic credit card payment system established by theUnited States Department of Treasury.

2. Actions Subject to Electronic Case Filing.

All civil, criminal, miscellaneous cases and documents filed in this court on or after January 5, 2004, will be entered into the court's Electronic Case Filing ("ECF") System in accordance with these Policies and Procedures ("Procedures"). Except as expressly provided in these Procedures and in exceptional circumstances, all documents shall be filed electronically.

3. Initial Papers.

Complaints and Notices of Removal are to be filed electronically. Cases subject to sealing or restricted access (e.g., qui tam or social security) should be filed as a paper filing. All documents submitted as a paper filing must be accompanied by a disk or CD ROM containing the signed document in PDF format. In a case removed to the federal court, parties are requested to provide electronic copies of all documents previously filed in the state court. In criminal cases, the indictment, information, or complaint, including any superseders, warrant for arrest or summons, will be accomplished as a paper filing.

4. Service of Process

Service of summons and complaint must be made under Federal Rule of Civil Procedure 4 and applicable Local Rules governing service.

5. Eligibility, Registration, Passwords.

An attorney admitted to the Bar of this court, including attorneys authorized to represent the United States, may register as a Filing User by completing the prescribed registration form and submitting it to the Clerk of Court. Exceptions to this requirement are out-of-state attorneys who: 1) represent a party in an action transferred to New Jersey pursuant to an Order issued by the Judicial Panel on Multidistrict Litigation;[1] or 2) are retained to represent defendants in criminal cases. The form is available on the court's web site at www.njd.uscourts.gov. Registration as a Filing User constitutes consent to electronic service of all documents as provided in this Order in accordance with the Federal Rules of Civil Procedure and the Federal Rules of Criminal Procedure.

When registering as an ECF Filing User, an attorney is certifying that he/she has completed the ECF tutorial on the court's web site or some other form of training provided by the court. It is recommended that a PACER account be established, which can be accomplished by visiting the PACER web site at http://pacer.psc.uscourts.gov . After verification, the Filing User will receive an electronic notification of the user login and password. A Filing User shall protect the security of the User's password and immediately notify the court if the Filing User suspects that the password has been compromised.

A Filing User will promptly notify the court by e-mail to ecfchange@njd.uscourts.gov if there is a change in personal data, such as name, e-mail address, telephone number, etc., as required under Local Civil Rule 10.1.

The E-Filing Registration Form includes a field for the User's e-mail address. This e-mail address is essential in order to receive Notices of Electronic Filing. It can be the user's business or personal e-mail address. It can also be an e-mail address for another person designated to receive these Notices. If you change the e-mail address for receiving Notices of Electronic Filing, notify the Clerk's Office promptly by e-mail to ecfchange@njd.uscourts.gov.

Pro Se Parties - A party who is not represented by counsel must file documents with the clerk as a paper filing.

A Pro Se party who is not incarcerated may request to receive filed documents electronically upon completion of a "Consent & Registration Form to Receive Documents Electronically." The form is available on the court's web site at www.njd.uscourts.gov.

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[1] Pursuant to the General Rules of the Judicial Panel on Multidistrict Litigation, any attorney of record in any action transferred under Section 1407 may continue to represent his or her client in any district court of the United States to which such action is transferred; therefore, parties are not required to obtain local counsel in the district to which such action is transferred.

6. Consequences of Electronic Filing.

Electronic transmission of documents to the Electronic Filing System in accordance with these Policies and Procedures, together with the transmission of a Notice of Electronic Filing from the court, constitutes filing of the document for all purposes of the Federal Rules of Civil Procedure, the Federal Rules of Criminal Procedure, and the Local Rules of this court, and constitutes entry of the document on the docket kept by the Clerk under Federal Rules of Civil Procedure 58 and 79 and Federal Rules of Criminal Procedure 49 and 55.

Before filing a scanned document with the court, a Filing User must verify its legibility.

When a document has been filed electronically, the official record of that document is the electronic recording as stored by the court. A document filed electronically is deemed filed on the date and time stated on the Notice of Electronic Filing from the court.

Filing a document electronically does not alter the filing deadline for that document. Electronic filing must be completed before midnight Eastern time in order to be considered timely filed that day. In accordance with Rule 6(e) of the Federal Rules of Civil Procedure and Rule 45(c) of the Federal Rules of Criminal Procedure, service by electronic means is treated the same as service by mail for the purposes of adding three (3) days to the prescribed period to respond.

7. Entry of Court Orders and Related Papers.

All orders, decrees, judgments, and proceedings of the court entered or issued by the court will be filed in accordance with these Policies and Procedures, and such filing shall constitute entry on the docket kept by the clerk under Federal Rules of Civil Procedure 58 and 79 and Federal Rules of Criminal Procedure 55.

All orders will be filed electronically by the court or court personnel. An order filed electronically signed with an s/ shall have the same force and effect as if the judge had affixed a handwritten signature.

The assigned judge or the clerk's office, if appropriate, may grant routine orders by a text-only docket entry for which a Notice of Electronic Filing will be generated. In such cases, no PDF document will be issued, and the text-only entry shall constitute the court's only order on the matter.

A Filing User submitting a proposed order to a motion should submit the document as an electronic attachment to the motion. Any other type of proposed order should be submitted in accordance with the procedure for a "Proposed Order" as outlined in the court's ECF User Manual.

8. Notice of Court Orders and Judgments.

Immediately upon the entry of an order or judgment in an action, the clerk will transmit to Filing Users in the case, in electronic form, a Notice of Electronic Filing. Electronic transmission of the

Notice of Electronic Filing constitutes the notice required by Federal Rules of Civil Procedure 77(d) and Federal Rules of Criminal Procedure 49(c).

9. Attachments and Exhibits.

A Filing User must submit in electronic form all documents referenced as exhibits or attachments, including briefs, in accordance with the court's ECF User Manual, including file size limitations contained therein, unless otherwise ordered by the court. A Filing User shall submit as exhibits or attachments only those excerpts of the referenced documents that are directly germane to the matter under consideration by the court. Excerpt materials must be clearly and prominently identified as such. The court may require parties to file additional excerpts or the complete document.

10. Courtesy Copies.

In addition to the electronic filing of all motion papers, including briefs, in support of or in opposition to a motion, the filer must submit forthwith to the Judge's or Magistrate Judge's chambers one courtesy copy of a filed paper or brief in paper form without disk or CD-ROM, unless otherwise directed by the judicial officer. These documents shall be clearly marked as courtesy copies and mailed or delivered directly to chambers.

11. Sealed Documents.

(a) Sealing of Documents and Confidential Materials under Local Civil Rule 5.3. Effective September 1, 2005, the Court will no longer accept documents in civil cases as a paper filing under seal. On or after that date, any such documents must be submitted electronically and must be submitted in compliance with Local Civil Rule 5.3.

Unless otherwise provided by federal law, nothing may be filed under seal unless an existing order so provides or 5.3(c)(3) is complied with. FAILURE TO COMPLY WITH LOCAL CIVIL RULE 5.3 MAY RESULT IN A WAIVER OF ANY OTHERWISE VALID BASIS FOR SEALING AND MAY RESULT IN THE DOCUMENT IN ISSUE BECOMING PUBLICLY AVAILABLE. Note, that any properly sealed document will, absent further order, be available to all other counsel of record in the particular civil action.

(b) Sealing of Criminal Documents. A document subject to a sealing order or order of confidentiality must be submitted as a paper filing, in an envelope clearly marked "sealed," and shall be accompanied by a disk or CD-ROM containing the document in PDF format for filing by the Clerk's Office. A motion to file a document under seal may be filed electronically, unless prohibited by law. The order of the court authorizing the filing of documents under seal may be filed electronically, unless prohibited by law. A paper copy of the sealing order must be attached to the documents under seal and be delivered to the clerk.

12. Exceptions to Electronic Filing.

(a) Permissive Exceptions

The following documents may be excluded from the Electronic Filing System and filed solely on paper:

(1) In cases where the record of an administrative proceeding (excluding Social Security Cases as referred to in paragraph 18) or other prior proceeding must be filed with the court, such record may be served and filed in hard copy without prior motion and order of the court.

(2) A party may move for permission to serve and file as a paper filing documents that cannot reasonably be scanned.

(b) Mandatory Exceptions

The following documents are excluded from the Electronic Filing System and shall be filed solely as a paper filing:

(1) ADMINISTRATIVE RECORDS IN SOCIAL SECURITY CASES

(2) TRANSCRIPTS (by Official Court Reporters/Electronic Sound Recording System)

(3) GRAND JURY MATTERS:
The following documents are examples of grand jury matters:
A) Minute Sheets of swearing in and empanelment;
B) Grand Jury Returns;
C) Voting Slips;
D) Motions to quash subpoenas and orders ruling on them;
E) Motions to enforce subpoenas and orders ruling on them;
F) Motions for immunity and orders ruling on them;
G) Motions for appointment of counsel and orders ruling on them.

(4) WARRANTS ISSUED:
The following are examples of types of warrants issued:
A) Seizure Warrants;
B) Search Warrants;
C) Pen Registers;
D) Wire Tap Orders;

(5) SENTENCING MEMORANDUMS.

13. Signatures.

(a) **Attorney Signatures.** The user login and password required to submit documents to the Electronic Filing System serve as the Filing User's signature on all electronic documents filed with the court. They serve as the signature for purposes of Federal Rules of Civil Procedure11, all other Federal Rules of Civil Procedure, Federal Rules of Criminal Procedure, and the Local

Rules of this court, and any other purpose for which a signature is required in connection with proceedings before the court.

An electronically filed document, or a document submitted on disk or CD-ROM, and in compliance with Local Civil Rules 10.1 and 11.1, must include a signature line with "s/," as shown below.

s/ Jennifer Doe

No Filing User or other person may knowingly permit or cause to permit a Filing User's password to be used by anyone other than an authorized agent of the Filing User.

(b) **Multiple Signatures.** A document requiring signatures of more than one party must be filed electronically either by: (1) submitting a scanned document containing all necessary signatures; or (2) in any other manner approved by the court.

(c) **Non-Attorney Signatures.** A document requiring the signature of a non-attorney must be filed electronically by: (1) submitting a scanned document containing all necessary signatures; or (2) in any other manner approved by the court.

14. Retention Requirements.

A document that is electronically filed and requires an original signature other than that of the Filing User must be maintained as a paper filing by the ECF Filing User and/or the firm representing the party on whose behalf the document was filed until one year after all periods for appeals expire. On request of the court, the ECF Filing User or law firm must provide the original document.

15. Service of Documents by Electronic Means.

(a) Service of Process: Nothing in these Procedures shall affect the manner of filing and service of complaints (including third-party complaints) and the issuance and service of summonses, which in all civil actions shall continue to be filed, issued and served in paper form and in conformance with the Federal Rules of Civil Procedure and the Local Rules of this court.

(b) Other Types of Service:

(1) Filing User: Upon the electronic filing of a pleading or other document, the court's ECF System will automatically generate and send a Notice of Electronic Filing to all Filing Users associated with that case. Transmission of the Notice of Electronic Filing constitutes service of the filed document on Filing Users.

The Notice of Electronic Filing includes the time of filing, the name of the party and attorney filing the document, the type of document, the text of the docket entry, and an electronic link (hyperlink) to the filed document, allowing anyone receiving the notice by e-mail to retrieve the document automatically. If the Filing User becomes aware that the

Notice of Electronic Filing was not transmitted successfully to a party, or that the notice is deficient, e.g., the electronic link to the document is defective, the filer shall serve a copy of the filed document by e-mail, hand, facsimile, or by first-class mail postage prepaid immediately upon notification of the deficiency of the Notice of Electronic Filing. The submission of the Filing User Registration Form to the court constitutes consent to service of all papers via the court's electronic filing system as provided in Federal Rules of Civil Procedure 5(b) and 77(d), and the "Notice of Electronic Filing" that is automatically generated by the court's Electronic Filing System constitutes service of the filed document on Filing Users.

A certificate of service must be included with **all documents** filed electronically. The certification of service must indicate how service was accomplished, i.e., electronically and/or other means as provided in Federal Rule of Civil Procedure 5(b).

(2) Non ECF Filer

A Non ECF Filer is entitled to receive a paper copy of any electronically filed document from the party making such filing. Service of such paper copy must be made according to the Federal Rules of Civil Procedure, the Federal Rules of Criminal Procedure, the Local Rules of this court, and as set forth in the ECF User Manual.

(c) Time to Respond Under Electronic Service: In accordance with Rule 6(e) of the Federal Rules of Civil Procedure and Rule 45(c) of the Federal Rules of Criminal Procedure service by electronic means is treated the same as service by mail for the purposes of adding three (3) days to the prescribed period to respond.

16. Technical Failures.

The clerk shall deem the court's Electronic Case Filing web site to be subject to a technical failure if the site is unable to accept filings continuously or intermittently for more than one hour occurring after 12:00 noon (Eastern Time) that day. If a Filing User experiences a technical failure, the document may be submitted to the court that day in an alternative manner, provided that it is accompanied by an affidavit of the Filing User's failed attempts to file electronically at least two times at least one hour apart after 12:00 noon. The following methods of filing are acceptable as a result of **only the court's** technical failure:

(a) In person, by bringing the document to the Clerk's Office on paper accompanied by a disk or CD-ROM which contains the document in PDF format.

(b) Via electronic mail in PDF attachment, sent to the e-mail address for technical failures listed in the ECF User Manual.

(c) Through facsimile transmission to the Clerk's Office where the presiding judicial officer is stationed. When a Filing User subject to technical failure submits a document by fax, the document shall be filed electronically on the next business day. Please refer to the fax numbers listed in the ECF User manual.

The initial point of contact for a Filing User experiencing technical difficulty filing a document electronically shall be the court's ECF Help Desk at the toll free numbers listed in the ECF User Manual. When possible, the clerk will provide notice of all such technical failures on the court's web site.

A Filing User who suffers prejudice as a result of a technical failure may seek appropriate relief from the court.

17. Public Access.

A person may retrieve information from the Electronic Filing System at the court's Internet site, ecf.njd.uscourts.gov, by obtaining a PACER login and password. With the exception of social security cases, a person who has PACER access may retrieve docket sheets and documents in civil and criminal[2] cases. Retrieval of documents in **social security cases** [3]is limited and may only be accessed by counsel of record. Any case or document under seal shall not be available to the public through electronic or any other means.

18. Sensitive Information.

As the public may access certain case information over the internet through the court's Electronic Filing System, sensitive information should not be included in any document filed with the court unless such inclusion is necessary and relevant to the case. If sensitive information must be included, the following personal data identifiers **must** be partially redacted from the document, whether it is filed traditionally or electronically:

(1) the last four digits of the social security number and tax identification number;
(2) financial account numbers to the last four digits;
(3) names of minor children to the initials;
(4) dates of birth to the year; and
(5) home addresses to city and state.

In compliance with the E-Government Act of 2002, a party wishing to file a document containing the personal data identifiers specified above may either:

(1) File an unredacted version of the document under seal, or;

(2) File a redacted version of the document and file a reference list under seal. The reference list shall contain the complete personal identifier(s) and the redacted identifier(s) used in its (their) place in the filing. All references in the case to the redacted identifiers included in

---

[2] The Judicial Conference of the United States, has agreed to permit remote public access to electronic criminal case file documents filed after November 1, 2001.

[3] Documents in social security cases may be excluded from the redaction requirement as they are not electronically available to the public over the Internet, pursuant to the privacy policy of the Judicial Conference of the United States.

the reference list will be construed to refer to the corresponding complete personal data identifier. The reference list must be filed under seal, and may be amended as of right.

The court may still require the party to file a redacted copy for the public file. In addition, caution must be exercised when filing documents that contain the following:

(1) Personal identifying numbers, such as a driver's license number;
(2) Medical records, treatment, and diagnoses;
(3) Employment history;
(4) Individual financial information; and
(5) Proprietary or trade secret information.

Additional items for criminal cases only:

(6) Information regarding an individual's cooperation with the government;
(7) Information regarding the victim of any criminal activity;
(8) National security information; and
(9) Sensitive security information as described in 49 U.S.C. § 114(s).

Counsel are strongly urged to share this information with all clients so that an informed decision about the inclusion of certain material may be made. If a redacted document is filed, it is the sole responsibility of counsel and the parties to be sure that pleadings and other papers comply with the rules and orders of this court requiring redaction of personal identifiers. The clerk will **not** review each filing for redaction.

Counsel and the parties are cautioned that failure to redact personal identifiers and/or the inclusion of irrelevant personal information in a document filed with the court may subject them to the full disciplinary and remedial power of the court, including sanctions pursuant to Federal Rules of Civil Procedure 11.

19. Correcting Docket Entries.

Once a document is filed electronically, corrections to the docket can only be made by the Clerk's Office. The System will not permit the filing party to make changes to the document or docket entry once the transaction has been accepted. Only upon an Order of the Court can a document be removed or withdrawn from the ECF system.

Adopted January 5, 2004, Amended March 24,2005, Amended September 1, 2005. Amended October 1, 2006

Civ. RULE 5.3 PROTECTIVE ORDERS AND PUBLIC ACCESS UNDER CM/ECF

(a) Scope of Rule

(1) This rule shall govern any request by a party to seal, or otherwise restrict public access to, any materials filed with the Court or utilized in connection with judicial decision-making. This

Exhibit 14

FRC, JURY

U.S. District Court [LIVE]
Eastern District of TEXAS LIVE (Marshall)
CIVIL DOCKET FOR CASE #: 2:03-cv-00212-TJW

Medtronic Ave Inc, et al v. Cordis Corporation
Assigned to: Judge T. John Ward
Demand: $0
Related Case: 2:06-cv-00078-TJW
Cause: 31:3731 Fraud

Date Filed: 06/05/2003
Jury Demand: Plaintiff
Nature of Suit: 370 Fraud or Truth-In-Lending
Jurisdiction: Diversity

Mediator

Robert M Parker

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12/09/2003	52	Amended complaint by Medtronic Ave Inc , (Answer due 12/19/03 for Cordis Corporation) amending [1-1] complaint adding plaintiff, Medtronic USA Inc (ktd) (Entered: 12/09/2003)
01/08/2004	53	VACATED PER 92 ORDER FILED 9/22/04 ORDER granting [25-1] motion to join arbitration, denying [24-1] motion to stay Arbitration, denying [10-1] motion to stay litigation of count 4 pending completion of arbitration (signed by Judge T. J. Ward 1/7/04 cc: attys & tjw 1/8/04) (ktd) Modified on 9/22/2004 (ktd,). (Entered: 01/08/2004)
02/02/2004	54	Filed in Tyler Answer to paragraphs 4-7, 26-29 and 45-52 of the amended complaint by Cordis Corporation (ktd) (Entered: 02/04/2004)
03/18/2004	55	Memorandum Opinion and ORDER denying 9 Motion to Dismiss . Signed by Judge T. John Ward on 3/15/2004. (rvw,) (Entered: 03/18/2004)
03/25/2004	56	MOTION to Amend 1 Complaint - file Third Amended Complaint by Medtronic Ave Inc, Medtronic USA Inc. (exhibits not scanned)(Tendered) (ktd,) Modified on 3/26/2004 (ktd,). Additional attachment(s) added on 4/28/2005 (ch,). (Entered: 03/26/2004)
04/01/2004	57	ORDER granting 56 Motion to Amend complaint. The court orders the amended complaint to be filed. Signed by Judge T. John Ward on 4/1/04. (djh,) (Entered: 04/01/2004)
04/01/2004	58	THIRD AMENDED COMPLAINT against Cordis Corporation , filed by Medtronic Ave Inc, Medtronic Inc, Medtronic USA Inc.(kjr,) (Entered: 04/02/2004)
04/13/2004	59	NOTICE of Hearing: Scheduling Conference set for 5/4/2004 at 1:00 PM before Judge T. John Ward in Marshall, TX.(shd,) (Entered: 04/13/2004)
04/15/2004	60	NOTICE sua sponte of scheduling conference set for 5/4/04 at 1:00 p.m. in MARSHALL TX before the Honorable T John Ward; Proposed deadlines for docket control order and discovery order.(TJW) cc: attys (poa,) (Entered: 04/15/2004)
04/23/2004	61	MOTION for leave to Amend 1 Complaint; file Fourth Amended Complaint by Medtronic Ave Inc, Medtronic Inc, Medtronic USA Inc. (ktd,) (Entered: 04/26/2004)
04/23/2004	62	Filed in Tyler ANSWER to Third Amended Complaint by Cordis Corporation.(ktd,) (Entered: 04/28/2004)
04/28/2004	63	Filed in Tyler Unopposed MOTION "instanter" for Leave to File Excess Pages for its Motion to transfer patent claims to the District of Delaware pursuant to 28 USC 1406(a) and 1404(a) by Cordis Corporation. (ktd,) (Entered: 04/30/2004)
04/28/2004	64	Filed in Tyler under SEAL Cross-MOTION to Change Venue to the District of Delaware and in OPPOSITION to pla's motion to amend (part 1 of 2-part document) by Cordis Corporation. (ktd,) (Entered: 04/30/2004)
04/28/2004	65	Filed in Tyler under SEAL RESPONSE in Opposition re 61 MOTION to Amend/Correct 1 Complaint filed by Cordis Corporation. (part 2 of 2-part document) (ktd,) Modified on 4/30/2004 (ktd,). (Entered: 04/30/2004)
04/28/2004	66	Filed in Tyler under SEAL Memorandum BRIEF in support of its 64 cross-motion to transfer filed by Cordis Corporation. (ktd,) (Entered: 04/30/2004)
04/29/2004	68	NOTICE of Hearing: Scheduling Conference RESET for 5/24/2004 at 1:00 PM before Judge T. John Ward in Marshall, TX.(shd,) (Entered: 04/30/2004)

Exhibit 15

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

MEDTRONIC VASCULAR, INC., f/k/a MEDTRONIC AVE, INC, MEDTRONIC, INC., and MEDTRONIC USA, INC.,	§	
Plaintiffs,	§	
v.	§	Civil Action No. 2:03-CV-212-TJW
CORDIS CORPORATION,	§	
Defendant.	§	Jury Trial Requested

PLAINTIFFS' FIFTH AMENDED COMPLAINT

Plaintiffs Medtronic Vascular, Inc., f/k/a Medtronic AVE, Inc. ("Medtronic AVE"), Medtronic, Inc. ("Medtronic"), and Medtronic USA, Inc. ("Medtronic USA") file this Fifth Amended Complaint against Cordis Corporation ("Cordis").

Nature of Case

1. This is a patent infringement case. As disclosed more fully in Plaintiffs' disclosures, Cordis's products infringe two of Medtronic AVE's patents. Plaintiffs incorporate Plaintiffs' Disclosure of Asserted Claims and Preliminary Infringement Contentions, dated June 7, 2006, by reference as though set forth here in full.

Parties

2. Plaintiff Medtronic AVE (now known as Medtronic Vascular, Inc.) is a Delaware corporation with its principal place of business in California. Plaintiff Medtronic is a Minnesota corporation with its principal place of business in Minnesota. Plaintiff Medtronic USA is a Minnesota corporation with its principal place of business in Minnesota. Medtronic and Medtronic USA sell stent delivery systems in the United States.

3. Defendant Cordis Corporation is a Florida corporation with its principal places of business in Florida and New Jersey. Cordis is transacting business in the Eastern District of Texas by using, selling, and/or offering for sale the Cypher Coronary Stent, other non-drug-eluting stents, and angioplasty products in this district or by transacting other business in this district.

Jurisdiction and Venue

4. This lawsuit is an action for patent infringement that arises under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. §§ 271 and 281-285. This controversy exceeds the sum of $75,000, exclusive of interest and costs, and is between citizens of different States. It also arises under the patent laws of the United States. Cordis has previously admitted that this Court has proper jurisdiction over this case. Thus, jurisdiction is conferred on this Court pursuant to 28 U.S.C. §§ 1331, 1332(a), and 1338(a).

5. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b). Cordis is transacting business and has committed patent infringement within the State of Texas and this district. Cordis has previously admitted in this case that it conducts business in this district under 28 U.S.C. §§ 1391 and 1400. Cordis's parent, Johnson & Johnson, and Cordis's affiliates have been sued in separate lawsuits in this district for their general business practices. Cordis has already filed two separate motions to transfer this case to two different venues outside of Texas. The Court has denied both of Cordis's motions to transfer venue. Cordis is therefore subject to the personal jurisdiction of this Court.

Factual Background

6. On February 20, 2001, the U.S. Patent and Trademark Office duly and legally issued United States Patent No. 6,190,358 B1 (the "'358 Patent") to Thomas K. Fitzmaurice,

entered, and a further award of post-judgment interest, pursuant to 28 U.S.C. § 1961, continuing until such judgment is paid, at the maximum rate allowed by law;

(e) permanent injunction against Cordis prohibiting any further infringement; and

(f) such other and further relief as this Court finds justified.

Respectfully submitted,

By: /s/ Mark L. Mathie
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ATTORNEYS FOR PLAINTIFFS MEDTRONIC AVE, INC. MEDTRONIC, INC., and MEDTRONIC USA, INC.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

MEDTRONIC AVE, INC., MEDTRONIC, INC. and MEDTRONIC USA, INC. Plaintiffs, v. CORDIS CORPORATION Defendant.	C.A. No. 2:03-CV-212-TJW

DEFENDANT'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' FIFTH AMENDED COMPLAINT

Defendant Cordis Corporation ("Cordis") answers the Fifth Amended Complaint of Plaintiffs Medtronic Vascular, Inc., f/k/a Medtronic AVE, Inc., Medtronic, Inc. and Medtronic USA, Inc. ("AVE") as follows:

NATURE OF CASE

1. Cordis admits that the Fifth Amended Complaint purports to state a claim for patent infringement. Cordis denies all remaining allegations of Paragraph 1.

PARTIES

2. Cordis admits the allegations of Paragraph 2 on information and belief.

3. Cordis admits that it is a Florida corporation organized and existing under the laws of the State of Florida with a principal place of business at 14201 N.W. 60th Avenue, Miami Lakes, Florida 33014. Cordis also admits the allegations in the second sentence of Paragraph 3, but denies the remaining allegations in this paragraph.

JURISDICTION AND VENUE

4. Cordis admits that the Fifth Amended Complaint purports to state a claim for patent infringement arising under the patent laws of the United States over which this Court has

Dated: December 6, 2006

Respectfully submitted,

/s/Eve L. Henson

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